

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	: Brad S. Culbert et al.
App. No	: 10/623,193
Filed	: July 18, 2003
For	: METHOD AND APPARATUS FOR SPINAL FIXATION
Examiner	: Anuradha Ramana
Art Unit	: 3775
Conf No.	: 2665

**DECLARATION UNDER 37 C.F.R. §1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Atiq Durrani, declare that:

1. I am an Orthopaedic Surgery Spine Surgeon and Specialist working with the Center for Advanced Spine Technologies (CAST) in Cincinnati, Ohio, and the Christ Hospital in West Chester, Ohio. I founded CAST in to provide an innovative spine-specific center where a patient can receive the absolute finest in care from spine-only specialists, along with the most advanced and proven spine technologies, treatments and procedures. Prior to CAST, I completed my undergraduate studies at Government College in Multan, Pakistan. I then completed my medical studies at the Army Medical College of Quaid-e-Azam International University in Islamabad, Pakistan. I later completed my residency at the University of Cincinnati in Cincinnati, Ohio. Finally, I also completed various fellowships, including those in the following areas: Spine Surgery at the Leatherman Spine Institute of the University Of Louisville in Louisville, Kentucky; Orthopedic Oncology at the University of Florida Medical Center in Gainesville, Florida; Pediatric Orthopedics & Scoliosis at the Texas Scottish Rite Hospital in Dallas, Texas; Pediatric Orthopedics at the Children's

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Hospital Medical Center in Cincinnati, Ohio; Infantile Spinal Deformities at the Royal National Orthopedic Hospital in Stanmore Middlesex, England; and Orthopedic Oncology at the Royal National Orthopedic Hospital in Stanmore Middlesex, England. *See* Exhibit 1. Through the course of my practice, I have become aware of the Applicants' innovative methods for providing spinal fixation.

2. I recently became a consultant for Applicant. I am paid on an hourly basis for my services.

3. As an orthopedic surgeon, I intimately involved in the treatment of spinal disorders and pain. Specifically, for over 18 years, I have been performing spinal fusion surgeries.

4. Transfacet fixation was described by King in 1948 (King D. Internal fixation for lumbosacral fusion. *J Bone Joint Surg Am.* 1948; 30:560-5). In this procedure, a screw extends through a facet of a first vertebra and into the facet of a second, typically inferior, vertebra. In 1959, a modified procedure, now called the Boucher technique, was introduced. In the Boucher technique, the screw is inserted through a facet of a first vertebra and then into a pedicle of a second, typically inferior, vertebra. In the 1980's, a translaminar technique was developed. In the translaminar technique, the screw extends through the spinous process and facet of a first vertebra and into the facet of a second, typically inferior, vertebra. In these techniques, the screw is often referred to as a "transfacet screw" and typically comprises simple an elongated body with a threaded distal end with a screw head at the distal end. As described above, the transfacet screw is passed through the facet of the first superior vertebra first and embedded into the facet or pedicle of the second inferior vertebra. Additional rotation of the transfacet screw causes the two bones to be compressed as a head of the screw contacts the first superior facet and the thread of the screw is screwed deeper into the facet or pedicle second inferior vertebra, thus bringing the two bones together. In this manner, the facet joint can be fused together to promote fusion between two vertebral bodies.

5. Theoretically, transfacet fixation has several advantages over traditional pedicle screw fixation systems. For example, transfacet screws can utilize truly minimally invasive techniques, which result in less patient trauma as compared to traditional pedicle screw fixation systems.

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6. However, in my opinion, the prior art transfacet screws failed to provide sufficient compression across the joint of an inferior vertebra and a superior vertebra, resulting in poor stabilization and/or osseointegration between the vertebrae. A further complication can arise when the transfacet screw was further rotated to compress the bones and the distal tip of the screw would often break through and protrude outwardly from within the inferior vertebra. For these reasons, there have been complications in spinal fixation procedures using transfacet screws. In my opinion, these shortcomings caused transfacet screws and their associates techniques described above to become disfavored amount orthopedic surgeons treating the spine. That is, while transfacet screws have been known since the 1960's as a technique for promoting fusion across the facet joint, up to a few years ago few orthopedic surgeons actually used this technique. I believe this was due to the shortcomings described above.

7. I have reviewed the prosecution history of the '193 Application including the most recent Final Office Action dated October 30, 2008, including U.S. Patent No. 5,527,312, issued to Ray (hereinafter "Ray") and U.S. Patent No. 5,989,255, issued to Pepper et al. (hereinafter "Pepper").

8. The '193 Application was filed on July 18, 2003. The '193 Application describes and claims a fixation device for use and spinal fixation. The fixation device comprises an elongate body having a bone anchor disposed at a distal end thereof. The fixation device also comprises retention structures on the body that are configured to engage complementary retention structures of a proximal anchor. The engagement between the retention structures allows the proximal anchor to be advanced along the body of the fixation device in a distal direction while preventing movement of the proximal anchor in a proximal direction. In some embodiments, the elongate body comprises first and second portions that are mechanically coupled to each other in order to allow the surgeon to grasp the second portion of the body while advancing the proximal anchor in a distal direction along the first portion of the body in order to provide secondary compression of the joint. In use, a joint between an inferior vertebra and a superior vertebra can be compressed without rotating the elongate body of the fixation device. For example, after the distal tip of the first portion of the elongate body has been positioned within the pedicle or facet of the inferior vertebra (usually accomplished by rotating a helical anchor into the pedicle or facet, thereby providing primary compression of the joint), the elongate body need not be rotated to achieve

additional or secondary compression across the joint. In addition, the distal tip of the device does not advance further when the secondary compression is applied. Importantly, this decouples the positioning of the tip of the device safely within the facet or pedicle from applying sufficient compression in the joint. Thereafter, the surgeon can detach or decouple the second portion from the first portion. This eliminates the problem (described above) associated with traditional transfacet screws of the distal tip of advancing completely through the facet or pedicle of the inferior vertebra. With respect to the claims, Claim 18 recites, in part, a method of providing spinal fixation comprising “advancing a bone anchor of the fixation device through a facet of a first vertebra to position a distal tip of the bone anchor within a pedicle of a second vertebra,” advancing the proximal anchor to apply compression between the facet of the first vertebra at the second vertebra, and “mechanically decoupling the second portion from the first portion after the proximal anchor is advanced distally along the fixation device.”

9. Ray (U.S. Patent No. 5,527,312) (Exhibit 2) provides an example of a prior art screw used in a spinal fixation system. In particular, Ray describes the challenges presented in performing spinal fusion when a patient has undergone a laminectomy. Ray points out that translaminar screws are inadequate to fixate an intervertebral joint. Because of the laminectomy, the lamina of the superior vertebra is generally weak, and the translaminar screws can cause breakage in the lamina, thus destabilizing the fixated joint. As such, Ray discloses a method of spinal fixation in which pairs of fixation bars are used to stabilize pairs of screws to fixate the intervertebral joint when a laminectomy has been performed. In particular, each screw passes through an aperture of a fixation bar that is hooked over and around the pedicle of the superior vertebra. *See* Ray, col. 2, line 50 – col. 3, line 9. The first screw is advanced on the left side of the sagittal plane through the lamina of a superior vertebra and into the left base of the transverse process of an inferior vertebra, thereby fixing the position of the first fixation bar. *See id.* at col. 2, lines 35-41. Further, the second screw it is advanced on the right side of the sagittal plane through the lamina of the superior vertebra into the right base of the transverse process of the inferior vertebra, thereby fixing the position of the second fixation bar. *See id.* at col. 2, lines 41-47. In order to minimize lateral or transverse movement of the screw relative to the longitudinal axis of the screw, Ray uses the fixation bars. The fixation bars form a hook that extends over and

around the adjacent pedicle to secure the bar from movement in an inferior direction. *See id.* at col. 3, lines 3-6. As someone who understands the considerations involved in post-laminectomy spinal stabilization, I appreciate the benefits provided by the method disclosed in Ray. However, this method is directed at solving a problem that is generally unrelated to the problems solved through the present Application. Further, this method does not disclose the features and advantages provided by the methods disclosed in the present Application.

10. First, I note that the screw disclosed in Ray cannot provide secondary compression. The screw disclosed in Ray is a threaded elongate body with a head that is configured to receive a wrench, such as an Allen wrench. *See id.* at col. 3, lines 10-13 and Figures 1, 2, and 4. Further, although the method disclosed in Ray provides a method of fixing a fixation bar to stabilize adjacent vertebrae, Ray provides no teaching or other disclosure of how the screws are able to provide sufficient compression across the intervertebral joint in any situation, much less secondary compression. Much less, Ray fails to teach or otherwise disclose how the distal tip of the screw is prevented from exiting the transverse process of the inferior vertebra if the screws need to be further rotated to provide additional compression. Thus, Ray fails to teach or otherwise disclose any of the claimed methods of the present Application, including the steps of advancing the proximal anchor to apply compression between the facet of the first vertebra at the second vertebra or “mechanically decoupling the second portion from the first portion after the proximal anchor is advanced distally along the fixation device” as recited in Claim 18.

11. In addition to the fact that the screw disclosed in Ray cannot provide secondary compression, as one of skill in the art, I cannot see why one of skill would seek to apply axial compression along the axis of the screw disclosed in Ray. Ray is concerned about minimizing lateral or transverse movement—not axial or longitudinal movement—of the screw relative to the longitudinal axis of the screw. That is why Ray discloses the use of the fixation bars, to minimize lateral movement of the screws. The fixation bars form a hook that extends over and around the adjacent pedicle to secure the bar from movement in an inferior direction. *See id.* at col. 3, lines 3-6. This arrangement resists lateral or transverse “toggling” of the screw, as can be appreciated by reference to Figure 1 in Ray. However, the method disclosed in the present Application seeks

to apply compression or prevent movement along the axial or longitudinal direction of the fixation device. In other words, Ray is only concerned with minimizing lateral movement, not axial movement of the screw relative to the longitudinal axis of the screw. Ray simply does not disclose or otherwise teach any reason or benefit for providing compression along the longitudinal axis of the screw.

12. In addition, I also note that Ray specifically discloses the screws are advanced through the lamina of the superior vertebra and into the transverse process of the inferior vertebra. *See id.* at col. 2, lines 35-47. As one of skill in the art, I would not construe this disclosure as teaching or otherwise providing any reason to advance a bone fixation device, such as that disclosed in the present Application, through the facet of the superior vertebra and into the pedicle of the inferior vertebra, as generally recited in the claimed methods. Further, I note that the final Office Action indicates that, Ray discloses a method wherein “the screw is advanced through a first vertebra into the pedicle of a second vertebra.” *See* Office Action, page 3. Contrary to this assertion, as one of skill in the art, I believe it is clear that Ray discloses that the screws are advanced into the transverse process of the inferior vertebra, which is functionally and structurally different from the pedicle, and avoiding the pedicle. In contrast to Ray, the claimed methods of the present Application recite that the bone anchor extends into the pedicle of the inferior vertebra.

13. Pepper (U.S. Patent No. 5,989,255) (Exhibit 3) is directed to an orthopedic bone screw apparatus and a method of implantation. *See* Pepper, Abstract. The bone screw apparatus of Pepper is capable of applying axial or secondary compression. However, as one of skill in the art, I see no reason why a person of skill in the art would combine the teachings of Pepper and Ray. Even so, I do not believe that Pepper suggests any possible modification to Ray that would produce any of the claimed methods of the present Application. For example, nothing in Pepper suggests changing the angular orientation of the screws disclosed in Ray (away from the lamina to transverse process axis, as disclosed in Ray) to an angular orientation as claimed in the present Application (toward the native facet and along to the pedicle axis). Even if one of skill has a reason to combine Pepper with Ray, the combination of the teachings of Pepper and Ray would not disclose or suggest the methods claimed in the present Application. Instead, such a

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combination of Pepper and Ray would produce a modified Ray method in which the Pepper compression screw passes into the lamina of a laminectomy patient, extends into the transverse process, and is linked with the fixation bar. The combination of Ray and Pepper would fail to disclose or suggest the claimed invention.

14. It is my belief that one of skill in the art of would not be motivated to combine Ray with Pepper as indicated in the Office Action.

15. Moreover, as one of skill in the art, it appears to me that the Examiner is not appreciating the long-present problem or the unique solution provided and described in the '193 Application. At the time of the invention, there was a long felt, but unresolved need "for an orthopedic fixation device for spinal fixation with improved locking force, which resists migration and rotation, and which can be easily and rapidly deployed within the spine." Present Application, ¶ [0009]. As discussed above, prior art transfacet screws failed to provide sufficient compression across the joint of the vertebrae. For example, as in Ray, many of these compression screws simply provided a first level of compression that was achieved by rotating the bone anchor into the inferior vertebra. However, because the bone anchor could only travel a limited distance within the inferior vertebra, one of two unacceptable outcomes was created in many cases: either the bone anchor broke through to the exterior of the inferior vertebra or the bone anchor was not advanced far enough to provide sufficient compression across the intervertebral joint. Although this problem was recognized since the 1960s, no one has developed a fixation device or procedure to solve these problems until the present application. In other words, despite being aware of these issues and competitions, no one in the medical community was able to resolve these issues for nearly 40 years. Moreover, as noted above, transfacet fixation had obvious theoretical advantages over traditional pedicle screw fixation techniques. Specifically, transfacet fixation could be done in much more minimally invasive manner as compared to traditional pedicle screw fixation. Now, given the claimed methods of the present Application, a surgeon can (1) achieve significantly more compression across the intervertebral joint than ever possible using the prior art compression screws, (2) do so without rotating the bone anchor from a dead center embedded

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position in the pedicle of the inferior vertebra and (3) achieve truly minimally invasive posterior fixation.

16. This invention solves this long felt, but unmet need by providing a method of spinal fixation, for example, according to: Claim 18 which comprises in part, “advancing the bone anchor of the fixation device through a facet of a first vertebra to position a distal tip of the bone anchor within a pedicle of a second vertebra,” advancing the proximal anchor over the body to apply compression between the first and second vertebrae and “mechanically decoupling the second portion from the first portion after the proximal anchor is advanced distally along the fixation device”; Claim 44 which comprises in part, “advancing the distal anchor of the fixation device through a facet of a first vertebra and into a pedicle of a second vertebra” and moving the proximal anchor distally over the body “thereby applying compression between the first and second vertebra”; and Claim 59 which comprises in part, “advancing the distal anchor of the fixation device through a facet of a first vertebra and into a pedicle of a second vertebra” and axially shortening the fixation device to “thereby applying compression between the first and second vertebra.” As discussed in the ‘193 Application, such methods can be performed by providing a fixation device whose distal tip or bone anchor can first be positioned within the pedicle of the inferior vertebra, and whose proximal anchor can subsequently be distally advanced along the device to provide secondary compression across the intervertebral joint. Thereafter, the surgeon can detach or decouple a second portion of the device from a first portion thereof. Thus, the claimed methods can be used provide compression that is far superior to what was available using prior art methods. Moreover, I know of no publications or product beside the present patent Application that addresses this problem as described in the present patent Application.

17. In August 2005, Interventional Spine began the first commercial implementation of the methods claimed in the ‘193 Application. The commercial product used in these methods was designated Bone Lok. The Bone Lok has an elongate body with a distal bone anchor, a proximal



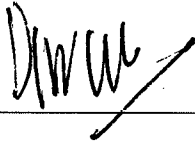
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anchor that advances along the elongate body to provide compression, and first and second portions of the elongate body that can be mechanically decoupled. *See* Exhibit 4.

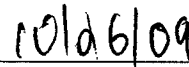
18. I am personally aware of several laudatory statements related to the spinal fixation procedures conducted as disclosed in the present Application.

19. All statements made herein of my own knowledge are true. All statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

[INSERT]

A handwritten signature in black ink, appearing to be 'D. W. W.', written over a horizontal line.

Date

A handwritten date '10/26/09' in black ink, written over a horizontal line.

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## **EXHIBIT 1**

# **CURRICULUM VITAE**

A.A. DURRANI, M.D.

## **PERSONAL**

**NAME:** Muhammad Abubakar Atiq Durrani

**DATE OF BIRTH:** 29 August 1968

**GENDER:** Male

**ADDRESS:** Center for Advanced Spine Technologies  
4555 Lake Forest Drive Suite 150  
Cincinnati, Ohio 45242  
[adurrani.yourspinedoctor@gmail.com](mailto:adurrani.yourspinedoctor@gmail.com)

## **EDUCATION**

### **SECONDARY SCHOOL EDUCATION** (March 1976 – March 1983)

LaSalle High School, Multan, Pakistan

Examinations: Catholic Board Secondary School Examination

Secondary School Certificate Examination

### **PRE-MEDICAL EDUCATION** (August 1983 – 1985)

Government College, Multan, Pakistan

Examination – Pre Medical Board Certificate Examination

### **MEDICAL SCHOOL** (April 1986 – Mar 1991)

Army Medical College, Quaid-e-Azam International University, Islamabad, Pakistan.

Examination: MBBS, Mar 1991.

National Board of Medical Examiners USA (NBME) September 1990

MD- Dec 1990

## **POST-GRADUATE TRAINING**

### **ORTHOPEDIC RESIDENCY TRAINING PROGRAM** July 1 1999- June 30 2003

University of Cincinnati, Department of Orthopedic Surgery, Cincinnati, Ohio USA.

## **FELLOWSHIP TRAINING:**

- (a) **Spine Surgery** ( Aug 1, 2003 – July 30, 2004)  
Leatherman Spine Institute, University Of Louisville, Louisville Kentucky
- (b) **Orthopedic Oncology** ( Jan 1, 1999 – June 30, 1999)  
University of Florida Medical Center, Gainesville, Florida, USA
- (c) **Pediatric Orthopedics & Scoliosis Fellowship** ( July 1, 1998 - December 1998)  
Texas Scottish Rite Hospital, Dallas, Texas USA

## **POST-GRADUATE TRAINING – (CONT'D)**

- (d) **Pediatric Orthopedics** (July 1, 1997 - June 30, 1998)  
Children's Hospital Medical Center, Cincinnati, Ohio USA
- (e) **Infantile Spinal Deformities** (Feb 7, 1997 – June 30, 1997 )  
Royal National Orthopedic Hospital Stanmore Middlesex, England
- (f) **Orthopedic Oncology** ( Aug 7, 1996 – Feb 6, 1997)  
Royal National Orthopedic Hospital Stanmore Middlesex, England

## **MEDICAL LICENSURE & CERTIFICATION**

State of Ohio License # 35-085087, Exp. 2009

State of Kentucky License # 39372, Exp. 2008

American Board of Orthopedic Surgery Certified, July 2007

## **ACADEMIC & HOSPITAL APPOINTMENTS**

Assistant Professor, Dept. of Orthopedic Surgery, University of Cincinnati, Cincinnati, OH.

Assistant Professor, Attending Orthopedic Surgeon, Children's Hospital Medical Center, Cincinnati, OH.

Clinical Director, Musculoskeletal Tumor Center, Children's Hospital Medical Center, Cincinnati, OH.

Co- Director, Center for Spinal Disorders, Children's Hospital Medical Center, Cincinnati, OH.

Fellowship Director, Cincinnati Spine Fellowship, (University of Cincinnati - Dept. of Orthopaedic/Neuro Surgery, Cincinnati Children's Hospital Medical Center - Division of Pediatric Orthopaedic Surgery, and the Mayfield Spine Institute), Cincinnati, OH.

Co-Director, Spine Institute, Christ Hospital, Cincinnati, OH

Co-Director, Durrani-Wylie Orthopaedic Basic Science Laboratory, Cincinnati, OH.

Courtesy Staff, The Christ Hospital

Staff Affiliate, University of Cincinnati

Courtesy Staff, Bethesda and Good Samaritan (Tri-Health)

Courtesy Staff, Mercy Hospital Mt. Airy

Courtesy Staff, The Jewish Hospital

Courtesy Staff, Fort Hamilton Hospital

## **AWARDS & HONORS**

Trustee of the University Orthopaedic Research and Education Foundation – November 2005

Candidate Fellow of the Scoliosis Research Society – November 2006-2011 Edgar Dawson

Traveling Fellowship of the Scoliosis Research Society – June 2006

Fellow American Academy of Orthopaedic Surgeons July, 2007

## **MEMBERSHIPS**

- (a) American Academy of Orthopedic Surgeons (AAOS)
- (b) American Medical Association (AMA)
- (c) American College of Surgeons
- (d) Orthopedic Research Society (ORS)
- (e) North American Spine Society (NASS)
- (f) Musculoskeletal Tumor Society (MSTS)
- (g) Mid America Orthopedic Association
- (h) Ohio State Medical Association (OSMA)
- (l) University of Florida Orthopedic Association

## **MEMBERSHIPS CON'T**

- (j) Texas Scottish Rite Hospital Orthopedic Alumni Association
- (k) International Neurofibromatosis Association
- (l) Scoliosis Research Society (SRS)
- (m) Spinal Deformity Study Group (SDSG), Associate Member Candidate

## **RESEARCH/BASIC SCIENCE**

### **CURRENT RESEARCH PROJECTS:**

- (a) Spinal Deformity Related Projects
  1. Local biochemical regulation of physal growth in a mouse model.
  2. Spatial and temporal mapping of the various zones of vertebral growth plate delineating the site and mode of action of various locally produced ligands, their receptors, activated pathways and the genes expressed during longitudinal bone growth in a mouse model.
  3. Identification of the biomechanical and the genetic signal for termination of vertebral growth in a mouse model.
  4. Correction of spinal deformity by modulation of vertebral growth through delivery of local growth in a rabbit model.
- (b) Intervertebral Disc Projects
  1. Spatial and temporal mapping of the various ligands, their receptors, activated pathways and the genes expressed in the intervertebral disc during physiological aging in a mouse.
  2. Effect of removal of nucleus pulposus cells on the annulus fibrosis in the intervertebral disc.
  3. Use of biological growth factors in restoration of intervertebral disc.
- (c) Musculoskeletal Oncology Related Projects
  1. Expression of vascular markers in aneurysmal bone cysts and their correlation to clinical response.
  2. Correlation of gene expression to clinical outcome in various sarcomas using the Tumor tissue bank.

### **Intramural/extramural GRANTS:**

1. Corporate Research Grant. "Clinical and Radiograph Outcomes of Pro-Dense for Cystic Bone Lesions," CCHMC. Funding by Wright Medical. \$120,000. March 2008. Principle Investigator.
2. Corporate Developmental Agreement. "MIS Deformity System" CCHMC. Globus Medical.
3. Corporate Research Grant. "Biological Regeneration for Intervertebral Disc," CCHMC. Funding by Globus Medical . \$1,500,000.00. March 2008. Key Developer.
4. UOREF Grant. Biomechanical Regulation of Postnatal Skeletal Growth, \$30,000; 2006-2007. Principle Investigator. CoPIs: J Sorger, S Sharif, G Mutema.
5. Cancer Free Kids Grant - CCHMC. Tumor Tissue Banking Project. \$20,000/4 years. Principal Investigator.
6. Clinical Opportunities Grant – Department of Surgery – CCHMC. \$125,916/year. Research project: "Regulation of Skeletal Growth Plate." September 2005. Principal Investigator.
7. Musculoskeletal Oncology Center and Research Foundation - "Clinical Opportunities Grant. CCHMC" , \$559,641 for 4 years. Research project: August, 2005, Principal Investigator.
8. University of Cincinnati Orthopedic Education and Research Fund. Research project: "Local biochemical regulation of physal growth in a rat model" Principal investigator.
9. Corporate Research Grant. " Biological Correction of spinal deformity without a spinal fusion," CCHMC. Funding by Johnson and Johnson. \$36,000/year for 3 years. Principal Investigator.

## **EDUCATIONAL GRANTS:**

1. Clinical Spine Fellowship Grant. CCHMC – Department of Orthopaedic Surgery. Funding by Synthes Spine. \$70,000/year.
2. Clinical Spine Fellowship Grant. CCHMC – Department of Orthopaedic Surgery. Funding by Medtronic Sofamor Danek. \$59,170/year.
3. Clinical Spine Fellowship Grant. CCHMC – Department of Orthopaedic Surgery. Funding by DePuy Spine. \$74,790/year.

## **PATENTS:**

- 1- Minimally access posterior spinal instrumentation and technique.
- 2- Correction of spinal deformity by local delivery of biological modulator proteins.
- 3- Expandable Vertebral Device with Can Lock.
- 4- Automatic lengthening Bone Fixation Device.

## **PUBLICATIONS**

### **SCIENTIFIC PUBLICATIONS**

Durrani AA, Katz DE : Factors that influence outcome in bracing large curves in patients with adolescent idiopathic scoliosis. *Spine* 2001 Nov 1;26(21):2354-61.

Durrani AA, Crawford AH, Choudhury SN, Saifuddin A, Morley TR: Modulation of Spinal Deformities in Patients with NF Type I. *Spine* 25(1) 69-75, January 2000.

Durrani AA, Dahia CL, Mahoney E, Wylie C: Postnatal growth, differentiation and aging of mouse intervertebral disc. *Spine* Mar 1 34(5): 447-455 2009

Durrani AA, Dahia CL, Mahoney E, Wylie C: Intercellular signaling pathways active in intervertebral growth aging and differentiation. *Spine* Mar 1 34(5): 456-462 2009

Kuntz C, Shaffery CL, Ondra SL, Durrani AA, : Spinal deformity: a new classification derived from neutral upright spinal alignment measurements in asymptomatic juvenile, adolescent adult and geriatric population. *Neurosurgery* 2008 Sep 63: 3 Suppl: 25-39 review.

### **CHAPTERS:**

Durrani AA, Glassman S: Indications for Surgical vs. Non-Surgical Treatment. *The Textbook of Spinal Surgery*, 3<sup>rd</sup> Edition. Bridwell K and DeWald R (eds). Lippincott Williams & Wilkins. Chapter 91, March 2008. In progress.

Durrani AA, Crawford AH: Pediatric spinal deformities ; *Atlas of endoscopic spine surgery* 2<sup>nd</sup> edition edited by Regan JJ, McAfee PC, Mack MJ).

Durrani AA, Crawford AH: Clubfoot ; *Orthopedic Knowledge update 2- pediatric orthopedics – AAOS*.

Crawford AH, Durrani AA: Surgical Management of Rigid Congenital Talipes Equinovarus (Clubfoot) IN: *An Atlas of Foot and Ankle Surgery*, 2nd Edition. Wulker N, Stephens MM, Cracchiolo A (eds). Taylor & Francis Group London and New York. Chapter 43, pp 387 – 397, 2005.

Durrani AA, Crawford AH, Schorry E: Outline and review on spinal deformities in Neurofibromatosis for Task force

## **PRESENTATIONS**

**Durrani AA**, Desai R, Crawford AH: How Effective is an All Screw Construct in Reducing the Rib Hump in Idiopathic Scoliosis. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

Dahia CL, Mahoney E, Wylie C, **Durrani AA**: Cell Signaling Pathways for Maintenance and Closure of Vertebral Growth Plates. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

Dahia CL, Mahoney E, Wylie C, **Durrani AA**: How Does Nucleus Pulposus Control the Annulus Fibrosis During Aging? SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

, **Durrani AA**, Desai R, Crawford AH: Outcome of Mast Transforaminal Lumbar Interbody Fusion (TLIF) for Symptomatic Juvenile Disc Disease. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

Dahia CL, Mahoney E, Wylie C, **Durrani AA**: Effect of Removal of Nucleus Pulposus Cells on the Annulus Fibrosis of the Intervertebral Disc. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

**Durrani AA**, Desai R, Crawford AH: Outcome of Direct Pars Repair in Competitive Athletes. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

**Durrani AA**, Desai R, Crawford AH: Lumbar Disc Herniation in Adolescent Athletes: A Prospective Analysis of Conservative Treatment vs. Microdiscectomy. SRS Eurospine Annual Meeting; Geneva, Switzerland, May 26-31, 2008.

**Durrani AA**, Desai R, Crawford AH: Outcomes of Direct Pars Repair in Adolescent Athletes. NASS 22<sup>nd</sup> Annual Meeting; Austin, Texas, October 23-27, 2007.

**Durrani AA**, Desai R, Crawford AH: Does Scheuermann's Kyphosis have a Psychological Impact? NASS 22<sup>nd</sup> Annual Meeting; Austin, Texas, October 23-27, 2007.

Dahia CL, Mahoney E, Wylie C, **Durrani AA**: Effect of Removal of Nucleus Pulposus Cells on the Annulus Fibrosis of the Intervertebral Disc. 14<sup>th</sup> Int'l. Meeting on Advanced Spine Techniques (IMAST); Paradise Island, Bahamas, July 11-14, 2007.

Dahia CL, Mahoney E, Wylie C, **Durrani AA**: Spatial and Temporal Localization of Components of the TGF, BMP, IHH and FGF Signaling Pathways in the Post-Natal Mouse Lumbar Vertebral Growth Plate (LVGP). 14<sup>th</sup> Int'l. Meeting on Advanced Spine Techniques (IMAST); Paradise Island, Bahamas, July 11-14, 2007.

**Durrani AA**, Desai R, Crawford AH: Prospective Analysis of Lumbar Microdiscectomy in Athlete Adolescents. 14<sup>th</sup> Int'l. Meeting on Advanced Spine Techniques (IMAST); Paradise Island, Bahamas, July 2007.

1. Durrani AA: Symptoms of the typical conditions to treat and/or treatment options.



- Seminar Series for the Spine Institute, Cincinnati, OH, February 27, 2008.
2. Durrani AA: Fixation/Fusion Techniques in Adolescent Idiopathic Scoliosis. ORS Annual Meeting, San Francisco, CA, February 24, 2008.
  3. Durrani AA: Reconstructive Options for Malignant Tumors in Skeletally Immature Patients. Grand Rounds; University of Cincinnati, Cincinnati, OH, November 14, 2007.
  4. Durrani AA: Outcomes of Direct Pars Repair in Adolescent Athletes. Special Interest Paper Presentation at the NASS 22<sup>nd</sup> Annual Meeting; Austin, Texas, October 23-27, 2007.
  5. Durrani AA: Neuromuscular Scoliosis. UC Peds Lecture Series; Cincinnati, OH, October 17, 2007.
  6. Durrani AA: Neck Pain in Athletes, OH/KY Outreach Program; West Chester, OH, September 19, 2007.
  7. Durrani AA: Back Pain in Athlete, OH/KY Outreach Program; Mason, OH, September 11, 2007.
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  21. Durrani A. Metastatic Bone Tumors. University of Cincinnati Grand Rounds, April 26, 2006,

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25. Durrani A. Fibrous Tumors of Bone, Orthopaedic Surgery Oncology Review Course. October 1, 2005, Cincinnati, OH.
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## **VISITING PROFESSORSHIPS**

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## **CONSULTANT AND EDITORIAL RESPONSIBILITIES**

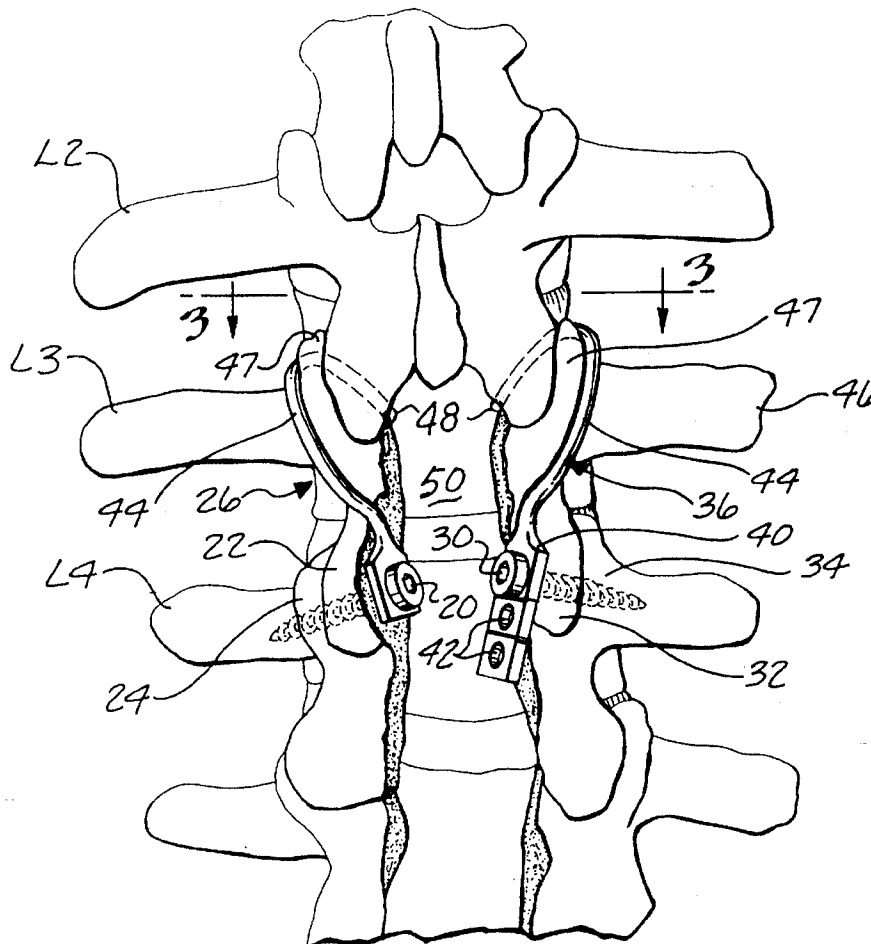
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Consultant for K2M  
Consultant for Spine Form  
Consultant for Wright Medical  
Consultant for Globus  
Consultant for Synthes Spine  
PI – Spine Staple Project

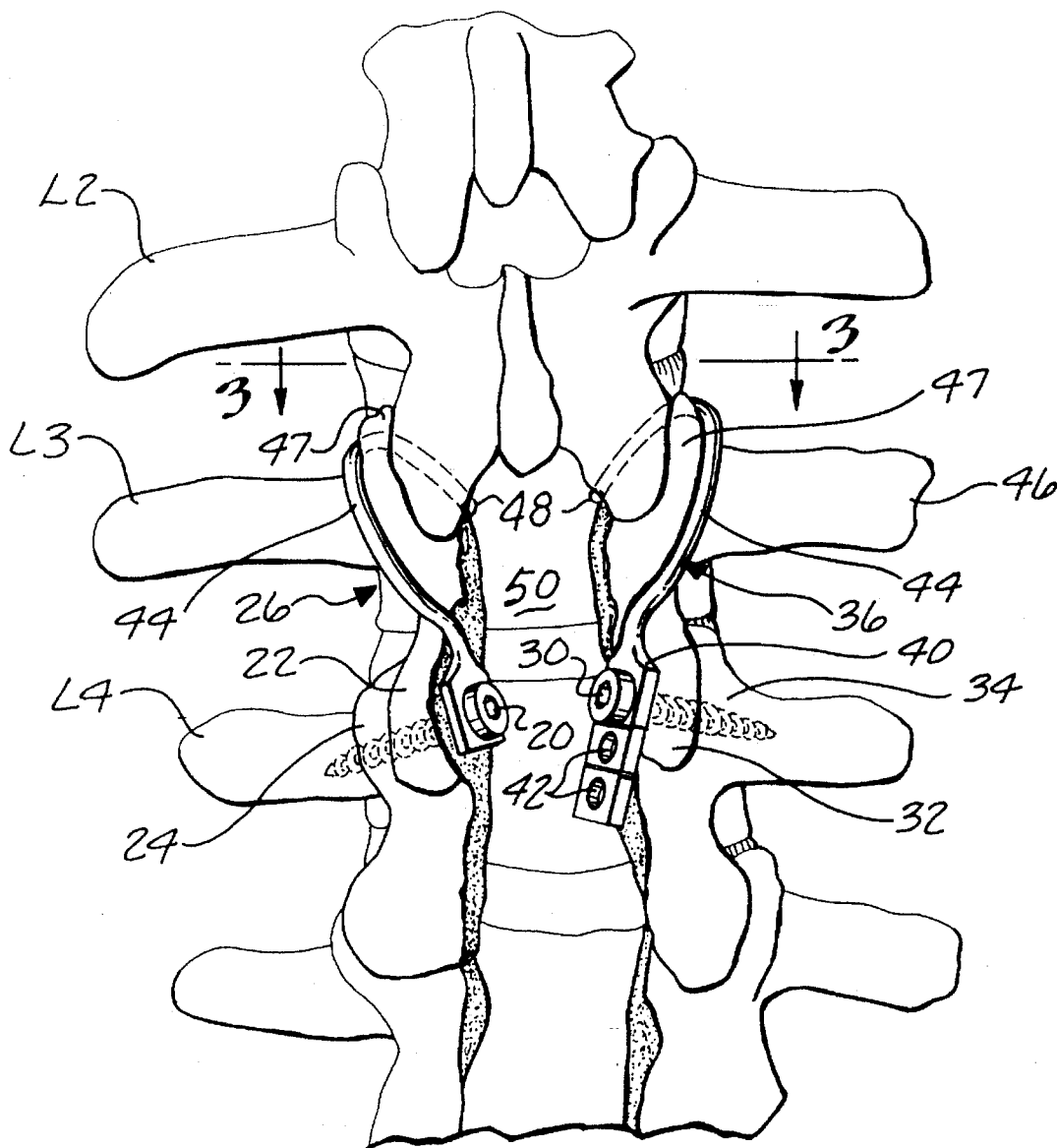
## **CURRENT HOSPITAL RESPONSIBILITIES**

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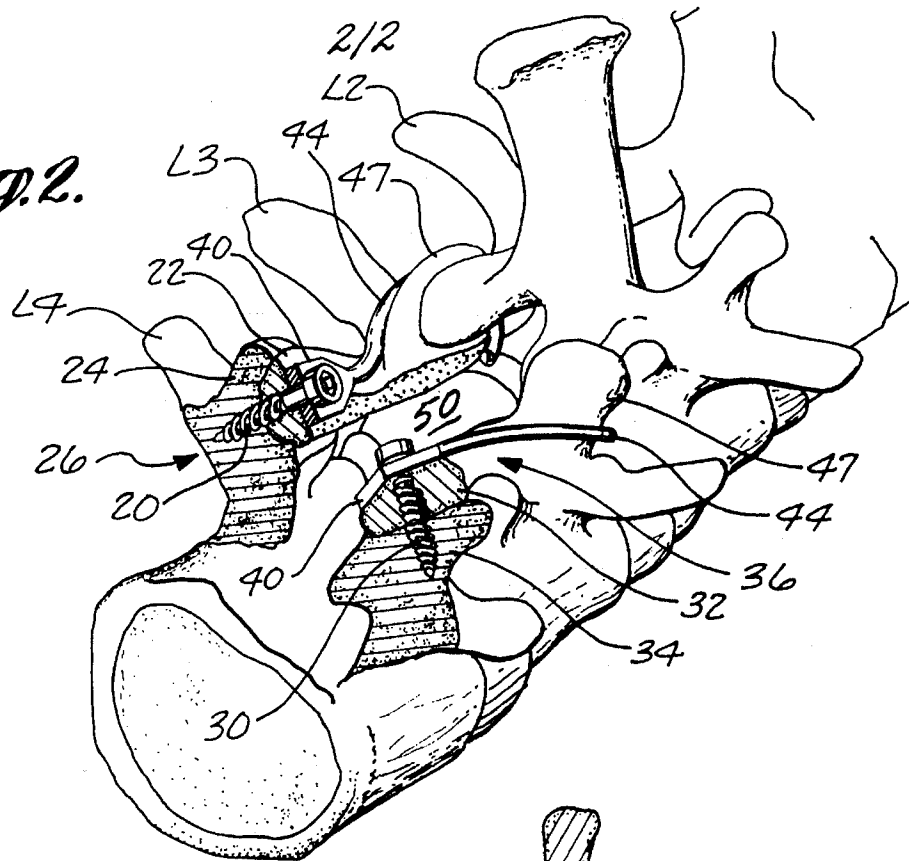
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## **EXHIBIT 2**

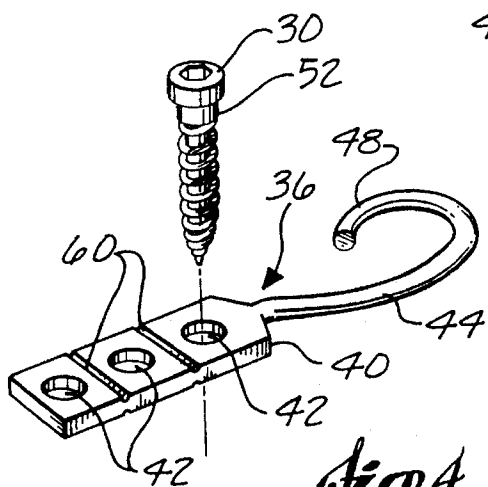
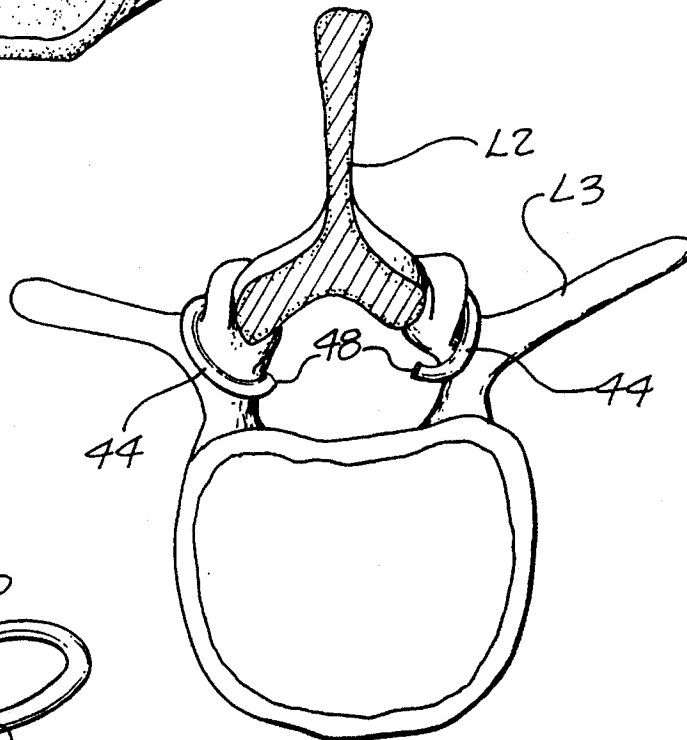


*Fig. 1.*

*Fig. 2.*



*Fig. 3.*



*Fig. 4.*

## FACET SCREW ANCHOR

## FIELD OF THE INVENTION

The present invention relates to surgical devices and methods for reducing deformities of the spine and, more particularly, for fixing two vertebrae relative to each other and holding the same while a fusion of two or more vertebrae heals.

## BACKGROUND OF THE INVENTION

Spinal fusions are indicated where a natural spinal deformation has occurred, where there has been damage to intervertebral disks, or where fracture of a vertebra has occurred. One method for fixing vertebrae relative to each other is disclosed in copending patent application Ser. No. 08/075,239, filed Jun. 10, 1993 now U.S. Pat. No. 5,470,333. With the fixation device disclosed therein, one or two plates are secured to the sacrum and a single rod extends from the sacral plates superiorly along the sagittal plane posterior to the spine. Transverse bars are rigidly secured to the rod at a location posterior to the vertebra to be fixed. The lateral extensions of these transverse bars are secured bilaterally by screws to the pedicles of the vertebra to be immobilized during the fusion process.

For some deformations and injuries, application of a spinal plate with a superiorly extending rail with transverse bars and pedicle screws are not required. Another method suggested by Magerl for fixation of successive vertebrae is to use translaminar screws. Conventionally, these translaminar screws extend through the spinous process and then through the lamina at the facet joint into and through the pedicle of the successively inferior vertebrae. Oftentimes a deformity and/or injury requires a laminectomy to eliminate nerve root compression, such as occurs with degenerative spondylolisthesis. When a laminectomy is required, the spinous process and the underlying lamina are removed. When the spinous process is removed, translaminar screw fixation is not generally adequate to stabilize successive vertebrae pending healing of the spinal fusion. This is because the lamina of the superior vertebra is generally relatively weak, especially where a laminectomy has been performed. Because the lamina is relatively weak, the translaminar screws can toggle relative to the superior vertebra, causing breakage in the lamina around the screw and destabilization of the joint. Thus, where a laminectomy has been performed, use of a sacral/rod/pedicle fixation system, such as that described above, is normally required.

## SUMMARY OF THE INVENTION

The present invention therefor provides a system for stabilizing adjacent vertebra in the thoracolumbar and lumbar regions of the spine, and particularly, for fixing an inferior vertebra to a superior vertebra through the facet joint. The system includes a first facet screw extending through the inferior facet of the superior vertebra lateral to the sagittal plane and extending through the facet joint of the inferior vertebra into the base of the transverse process. A fixation bar is operably secured to the screw so as to prevent toggling of the screw relative to the bar. The bar has a finger that extends in a superior direction across the dorsal side of the transverse process of the superior vertebra. The finger continues by wrapping around the superior aspect of the pedicle of the superior vertebra and extends in an anterior direction, and preferably thereafter in an inferior direction, thus terminating in a hook-like structure that in combination

with the screw fixes the structure in position. Preferably, a second screw and fixation bar are applied to the vertebra on the opposite side of the sagittal plane to provide bilateral fixation.

## BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the present invention can be derived by reading the ensuing specification in conjunction with the accompanying drawings, wherein:

FIG. 1 is a dorsal view of a portion of the lumbar spine and the fixation system of the present invention viewing in an anterior direction;

FIG. 2 is an isometric view of the spine and the fixation system of the present invention hooking in a direction that is lateral, superior, and slightly anterior to the spine;

FIG. 3 is a sectional view of the spine and fixation system of the present invention taken along section line 3—3 of FIG. 1; and

FIG. 4 is an isometric view of the fixation bar forming a part of the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring conjunctively to FIGS. 1, 2 and 3, the present invention is described in relation to fixing the L3 and L4 vertebrae relative to each other. It is understood, however, that the invention is applicable to other vertebrae in the lumbar region, as well as the thoracolumbar junction. As shown, a laminectomy has been performed on the L3 and L4 vertebrae. Thus, the spinous process and the underlying lamina on each side of the sagittal plane have been removed, leaving only the outlying portion of the lamina transverse of the sagittal plane on both the L3 and L4 vertebrae. In accordance with the present invention, a first facet screw 20 is inserted through the lamina 22 of the L3 vertebra in the region of the facet joint on the left side of the sagittal plane. The screw 20 extends in an anterior direction through the facet joint and angles laterally outwardly into the left base of the transverse process 24 of the inferior vertebra L4. A second facet screw 30 extends in an anterior direction through the lamina 32 on the opposite (right) side of the sagittal plane. The screw 30 extends through the facet joint on the right side of the sagittal plane and angles laterally outwardly into the right base of the transverse process 34 of the L4 vertebra. Thus, the screws 20 and 30 diverge in the anterior direction, and are also angled slightly in the inferior direction.

Each of the facet screws 20 and 30 are fitted with a fixation bar, 26 and 36 respectively. The fixation bars 26 and 36 are generally mirror images of each other. The fixation bars will first be described in conjunction with the bar 36 positioned on the right side of the sagittal plane. The fixation bar 36 includes an inferior portion 40 having a plurality of cylindrical bores 42. Each of the bores 42 are generally oriented along parallel axes and spaced in an inferior-superior direction along the inferior bar portion 40. The facet screw extends through one of the bores 42. By choosing the appropriate bore 42 for the facet screw, the relative length of the finger 44 can be varied to provide adjustability for different sized vertebra. The bar 36 has a finger 44 that extends in a superior, and slightly lateral, direction from the inferior portion 40. The finger extends in a superior direction across the dorsal side of the lateral process 46 of L3 and curves in a superior and anterior direction over the superior aspect of the lateral pedicle 47 of L3. The finger then extends



in an inferior direction and slightly laterally inwardly before terminating in an anterior end 48 short of the spinal cavity 50. The superior portion of the finger thus forms a hook that extends over and around the L3 pedicle to secure the bar from movement in an inferior direction as well as to prevent rotational movement about the longitudinal axis of the bar. The bar 26 on the left side of the sagittal plane form generally the mirror image of the stabilization bar 36 on the right side of the sagittal plane.

Referring to FIG. 4, a facet screw 30 is shown having a head 54 into which a suitable wrench, such as an Allen wrench, can be inserted to thread it through the facet joint. The portion 52 of the screw 30 adjacent the head is cylindrically shaped. The cylindrical portion 52 has a diameter that is slightly less than the diameter of the bores 42 so as to allow rotational and reciprocal movement of the screw in the bore, but not to allow the screw 30 to toggle relative to its longitudinal axis. Thus, the combination of the finger 44 wrapped around the superior portion of the lateral process 46 and the coaction of the screw holding the inferior portion 40 in place will prevent the toggling of the screw 30 relative to the lamina on the superior vertebra 43.

The inferior portion 40 of the bar 36 also carries a plurality of lateral weakened zones 60 in the form of lateral notches on both surfaces of the inferior portion 40 between each of the bores 42. With the manipulation of the proper tool, one or more sections containing bores 42 can be broken away from the stabilization bar to adjust the length of the inferior portion 40, so that unnecessary portions of the inferior portion can be removed. In FIG. 1, the stabilization bar 26 is shown with the lower two segments of the inferior portion removed.

The combined action of the two facet screws 30 and 20 in conjunction with the stabilization bars 26 and 36 will hold the facet screws rigidly relative to the L3 and L4 vertebrae and prevent toggling of the screws. Thus, even in the absence of a stabilizing bar tying pedicle screws to adjacent vertebrae or to the sacrum, and in the absence of translaminar screws that can extend through the spinous process, two vertebrae, such as L3 and L4, can be stabilized relative to each other pending the healing of a fusion.

The present invention has been described in conjunction with a preferred embodiment. It will be readily understood by one of ordinary skill that the various alterations, substitutions of equivalents, and other changes, can be made without departing from the broad concepts disclosed herein. It is therefore intended that the invention be limited only by the definition contained in the appended claims and equivalents thereof.

The embodiments of the invention in which an exclusive

property or privilege is claimed are defined as follows:

1. A system for stabilizing the thoracolumbar and lumbar region of the spine and for fixing an inferior vertebra to a superior vertebra, comprising:

- a first facet screw adapted to extend through the inferior facet of the superior vertebra lateral to the sagittal plane and to extend into the base of the transverse process of the inferior vertebra;
- a fixation bar operably secured to said screw so as to prevent toggling of the said screw relative to said bar, said bar having a finger configured and arranged to extend in a superior direction across the dorsal side of the transverse process of the superior vertebra, said finger adapted to wrap around the superior aspect of the pedicle of the superior vertebra and extend in an anterior direction and preferably thereafter in an anterior and inferior direction to terminate in a hook.

2. The system of claim 1, further comprising:

- a second facet screw adapted to extend through the inferior facet of the superior vertebra on the opposite side of the sagittal plane from the first facet screw and to extend into the base of the transverse process of the inferior vertebra;
- a second fixation bar operably secured to said second screw so as to prevent toggling of said second screw relative to said second bar, said second bar having a finger configured and arranged to extend in a superior direction across the dorsal side of the transverse process of the superior vertebra on said opposite side, said finger adapted to wrap around the superior aspect of the pedicle of the superior vertebra on said opposite side and extend in an anterior direction and preferably in an inferior direction to terminate in a second hook.

3. The system of claim 1, wherein said bar has a plurality of adjacent bores through which said facet screw can extend to adjust the length of the finger relative to the screw in a superior direction.

4. The system of claim 3, wherein said bar has weakened portions between each of said bores so that the portion of the bar inferior to the bore through which the facet screw extends can be broken away prior to application.

5. The system of claim 1, wherein said bar has at least one bore through which said screw can extend, said screw having a cylindrical shaft adjacent the head of the screw, said shaft being sized to rotatably and reciprocally fit in said bore and to prevent toggling motion of said screw relative to said bar.

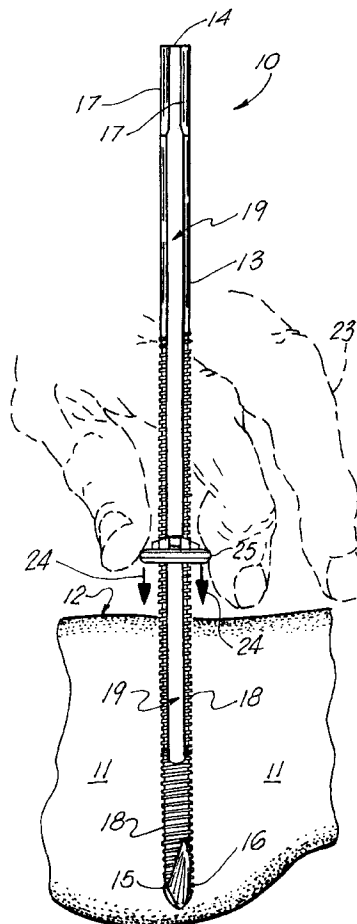
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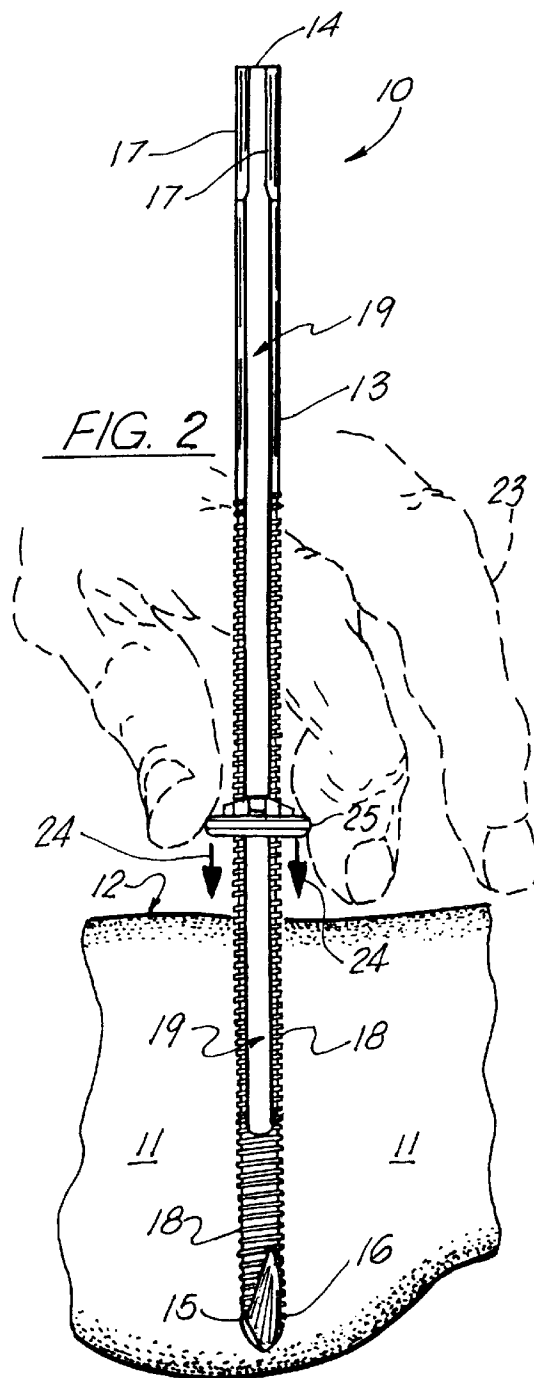
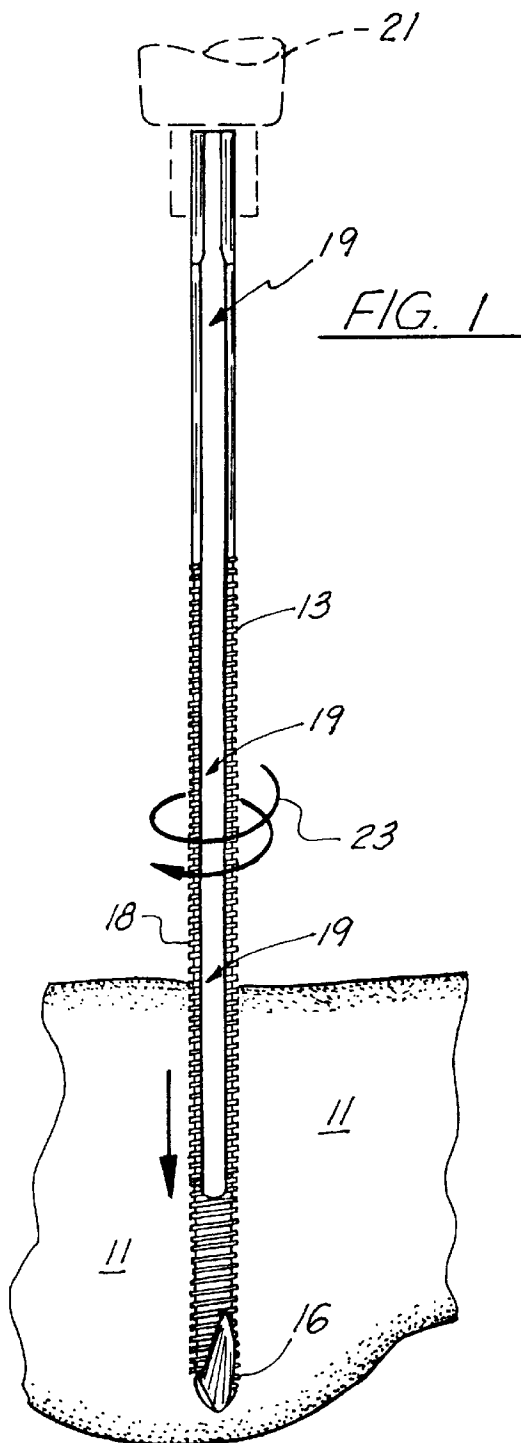
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### **EXHIBIT 3**

## [19]

[45] **Date of Patent:** **Nov. 23, 1999**





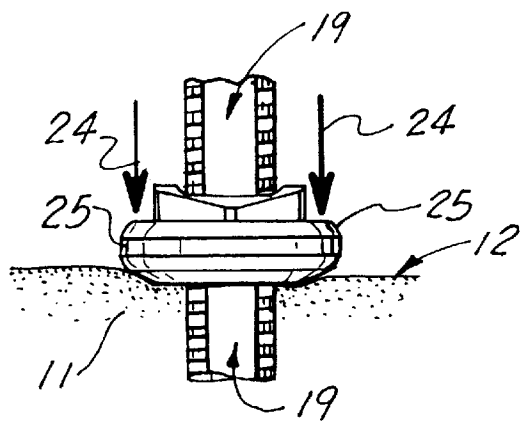


FIG. 4

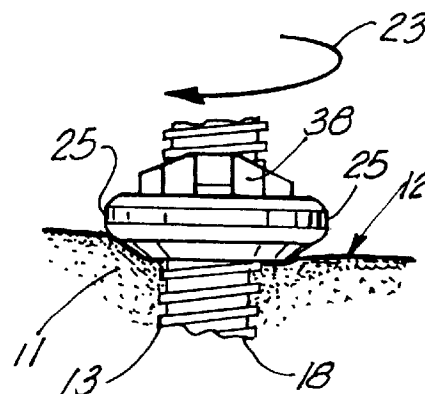


FIG. 5

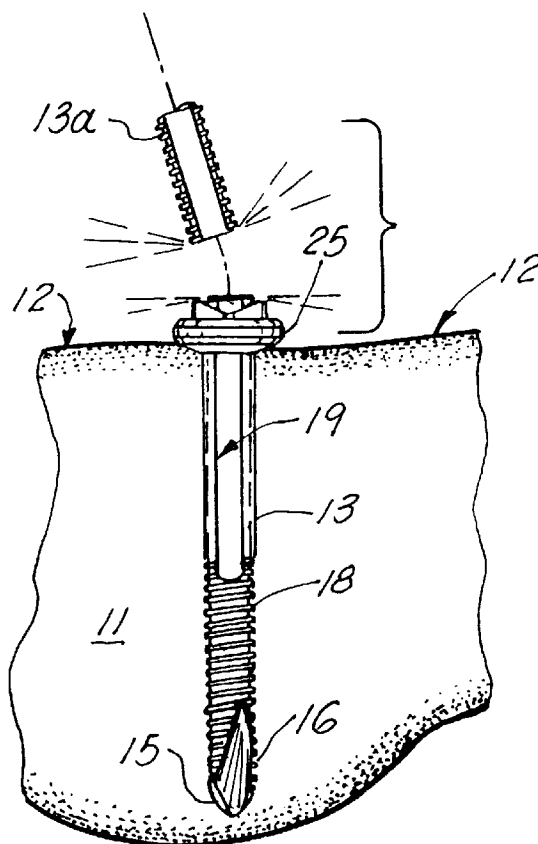


FIG. 3

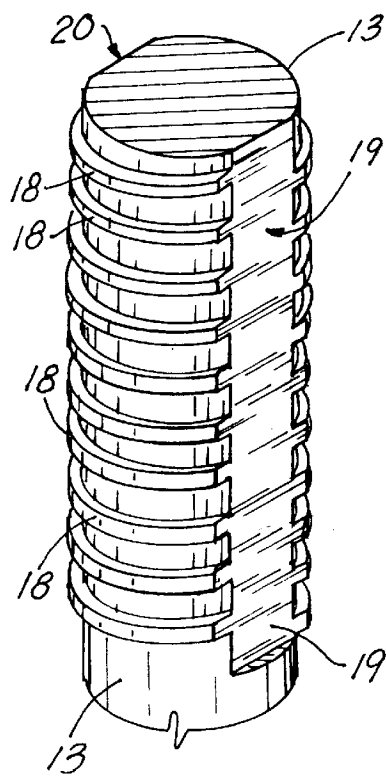


FIG. 6

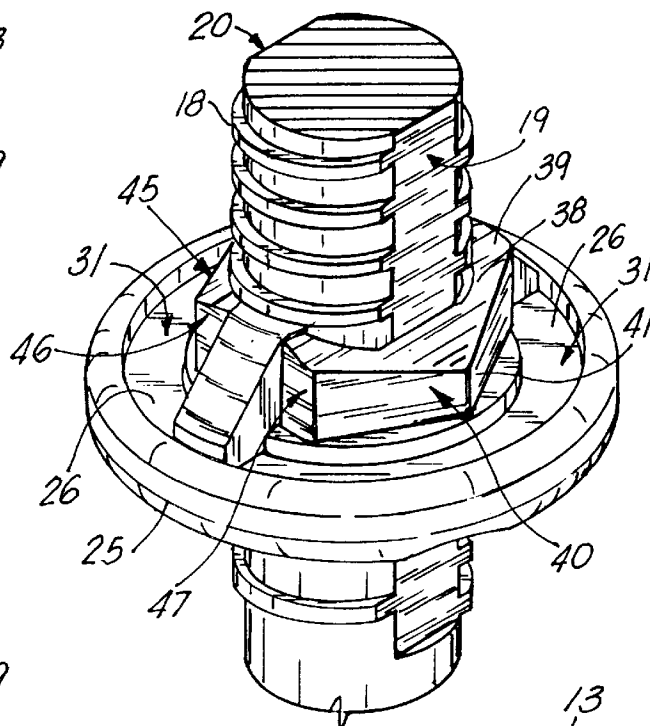


FIG. 7

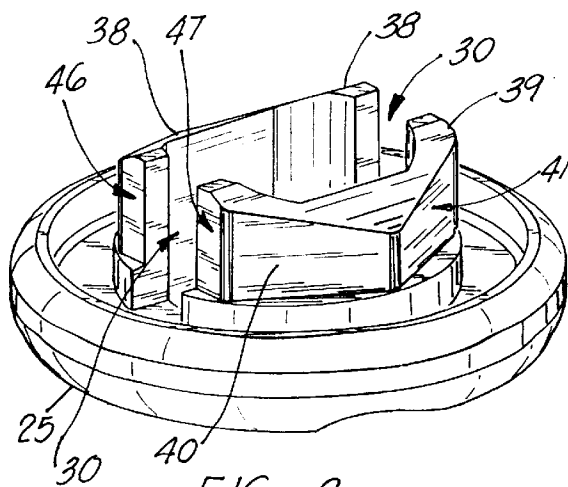


FIG. 8

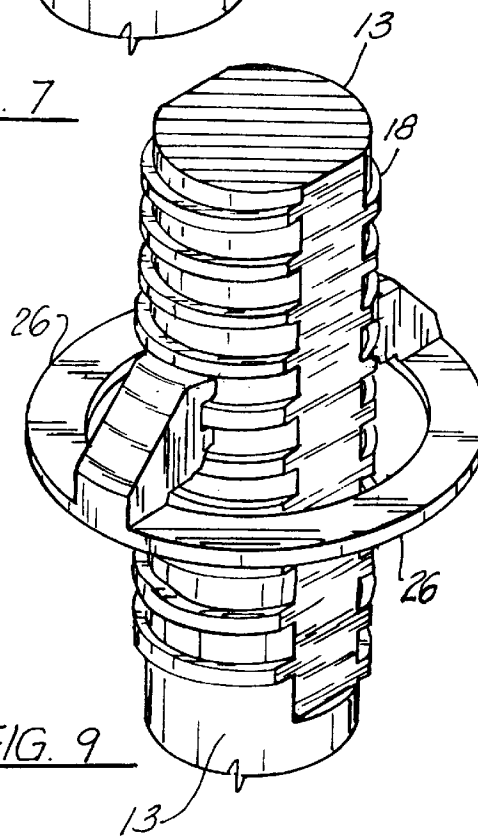


FIG. 9

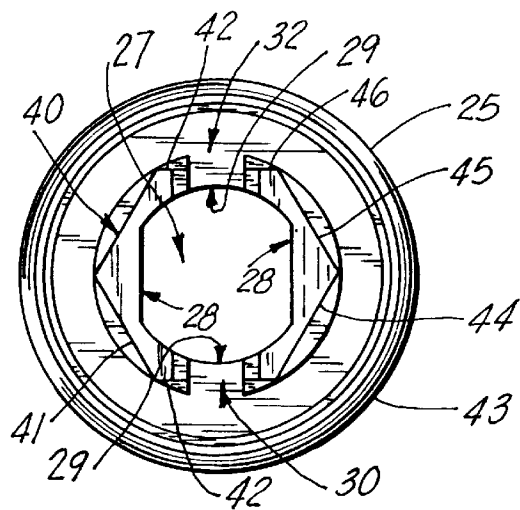


FIG. 10

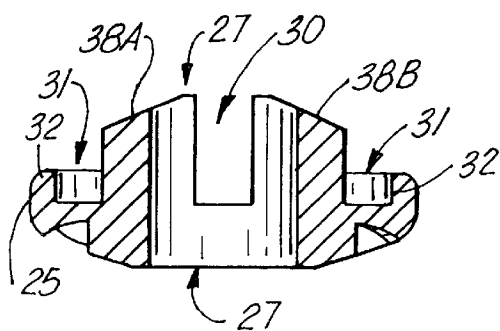


FIG. 11

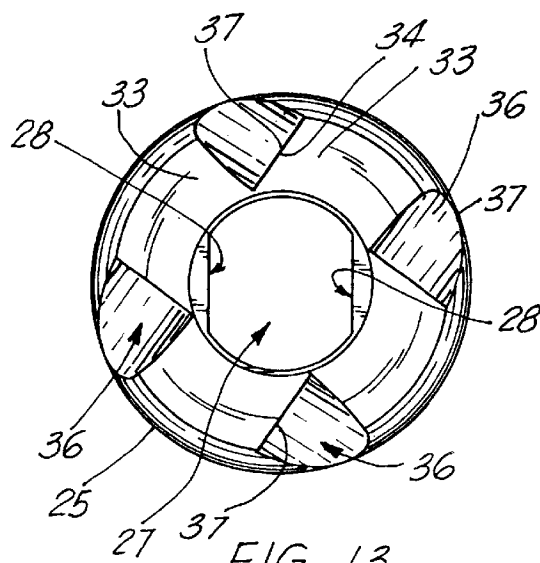


FIG. 13

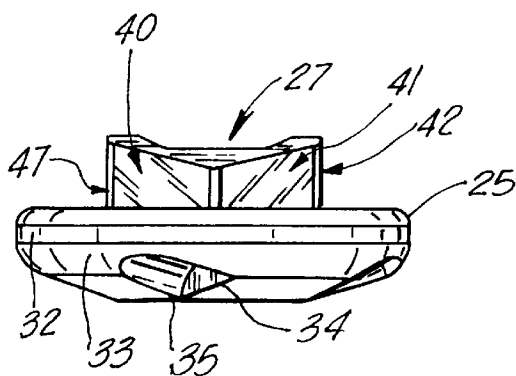


FIG. 12

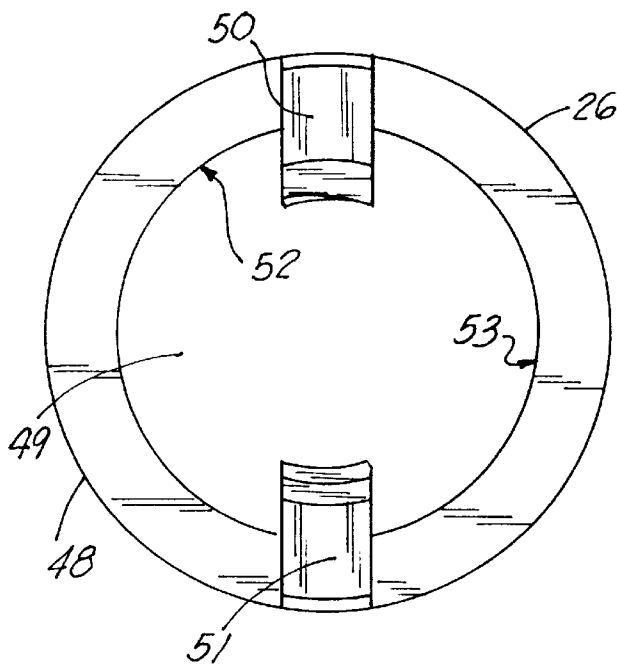


FIG. 14

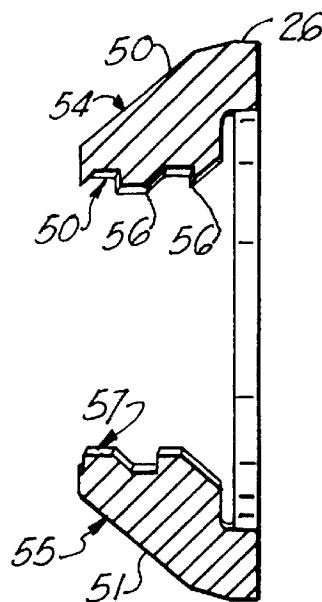


FIG. 15

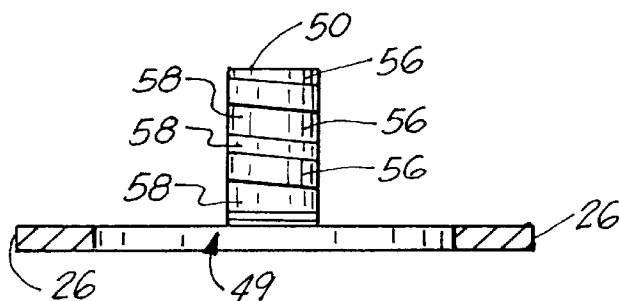


FIG. 16

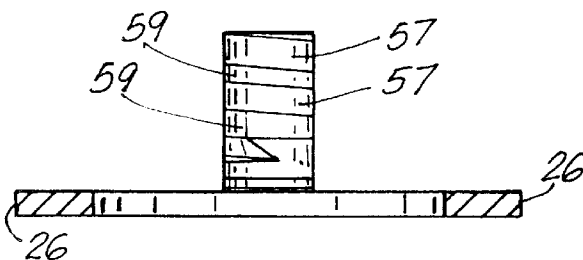


FIG. 17

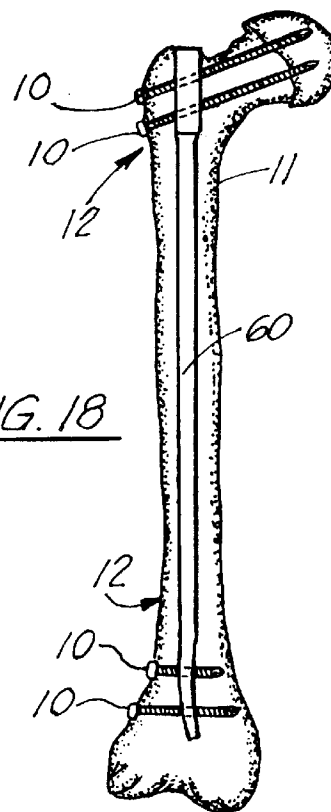


FIG. 18



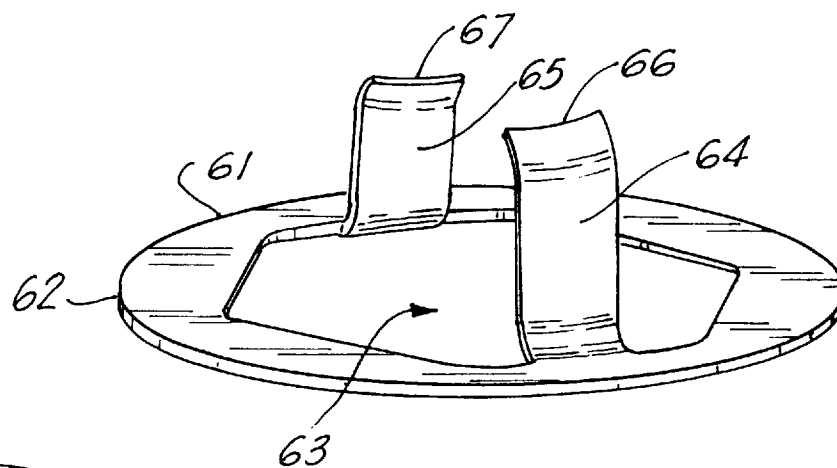


FIG. 19

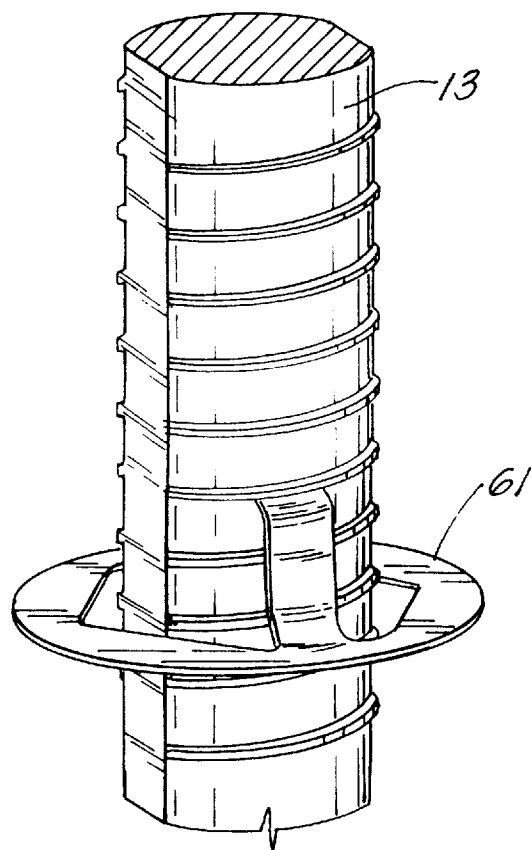


FIG. 20

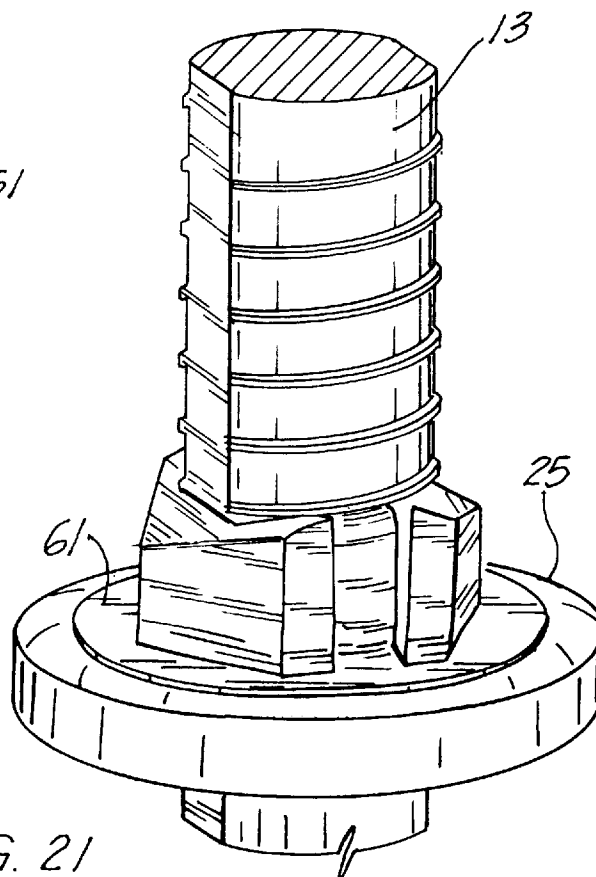


FIG. 21

**ORTHOPAEDIC DONE SCREW APPARATUS****CROSS-REFERENCE TO RELATED APPLICATIONS**

Not applicable.

**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT**

Not applicable

**REFERENCE TO A "MICROFICHE APPENDIX"**

Not applicable

**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates to orthopaedic bone screws and more particularly to an improved orthopaedic bone screw apparatus that can be custom fitted to a patient's bone tissue by two moving parts of the bone screw apparatus that include an elongated shank and a shaped head portion that slides over the shank. More particularly, the present invention relates to an improved orthopaedic bone screw apparatus having an elongated shank and sliding head portion with a ratcheting washer that fits over the shank and enables movement in one direction toward the patient's bone tissue but disallows sliding movement in the opposite direction.

**2. General Background of the Invention**

During orthopaedic surgery, bone screws are often employed. Some bone screws are embedded deep into a patient's bone tissue for affixing implants to the patient's bone tissues such as intramedullary nails. The surgeon does not always know exactly the thickness of a patient's bone tissue will be such as for example of thickness of a patient's femur. Therefore, it would be desirable for the surgeon to be able to custom size a bone screw to fit a particular patient during a particular operation.

A published PCT application PCT WO98/01079 discloses a cortical bone screw assembly comprising a shaft with a threaded section and a cutting and self-tapping end section. The assembly includes a nut which includes a resilient body. The resilient body can expand to allow translational movement of the nut along the shaft, but when such radial expansion is prevented so is such translational movement. However, the nut can still be moved along the shaft by rotation on the thread. This enables the nut to be advanced rapidly along an exposed length of shaft, but when it enters a restricted volume which prevents expansion of the resilient body, further advance can only be achieved by relative rotation.

**BRIEF SUMMARY OF THE INVENTION**

The present invention provides an improved bone screw apparatus for use in orthopaedic surgery. The apparatus includes an elongated shaft having proximal and distal end portions, the distal end portion having a cutting head, and the proximal end portion being sized and shaped to fit a driver tool such as a drill chuck.

The shaft is preferably externally threaded along at least a portion of its length. A plurality of longitudinally extending, circumferentially spaced apart surfaces extend along the shaft.

A removable head portion with a central opening enables the head to slide along the shaft.

A washer nests in an annular groove of the removable head portion. The washer has a pair of opposed ratcheting

members that only allow the washer to travel in a single direction when it is combined with the removable head portion.

This construction provides a means for preventing movement of the head along the shaft in a direction that would remove the head from the shaft proximally.

The removable head has an enlarged central annular portion that provides a number of flat surfaces thereon (for example eight) that define a place for attachment of a driver tool such as a hexagonally-shaped driver tool.

The tool receptive surface portion of the head includes intersecting external surfaces of the head that are spaced radially away from the shaft during use. These surfaces accept a driver tool for rotating the head and the connected shaft.

The shaft can be threaded along a majority of its length.

There are preferably two (2) longitudinally extending surfaces that are positioned about one hundred eighty (180°) degrees apart on the shaft.

A means for preventing movement of the head in one direction is defined by a pair of opposed arms with ratcheting portions thereon.

The head preferably has a convex annular distal surface that carries cutting blades thereon.

The washer provides internally threaded portions for engaging the external threads of the shaft.

The head and washer define a pair of independently movable, separable members.

A method of implanting with a bone screw to a patient's bone tissue is provided by the present invention.

The method includes the inserting of a bone screw shaft into a patient's bone tissue, the shaft having an external surface with shaped longitudinally extending portions thereon.

The method includes placing a removable head on the shaft after the shaft is embedded in step "a" by sliding the head proximally to distally along the shaft, until the head engages the patient's bone tissue.

The shaft can be severed proximally of the head once the shaft and head are in embedded in the selected bone tissue.

The head and shaft interlock and rotate together. Eventually, this enables surgeon to remove the assembly of shaft and head by rotating the head with a driver tool.

In the method of the present invention, a head is provided that is a two-part structure that includes first in second interlocking head segments and further comprising the step of connecting the first second head segments together.

The method can further comprise the step of engaging the threads of the shaft within internally threaded portion of the head. The shaft is preferably threaded along a majority of its length.

The method further comprises the steps of sliding the head to position next to the patient's bone tissue and the rotating the head relative to the shaft until the head engages and cuts the patient's bone tissue with cutting elements that countersink the head.

**BRIEF DESCRIPTION OF THE DRAWINGS**

For a further understanding of the nature, objects, and advantages of the present invention, reference should be had to the following detailed description, read in conjunction with the following drawings, wherein like reference numerals denote like elements and wherein:

FIG. 1 is a perspective elevational view of the preferred embodiment of the apparatus of present invention;

FIG. 2 is a perspective elevational view of the preferred embodiment of the apparatus of present invention showing the head and washer portions attached to the shaft portion;

FIG. 3 is a sectional elevational view of the preferred embodiment of the apparatus of present invention illustrating separation of the upper portion of the shaft after the head, washer and shaft have been surgically placed;

FIG. 4 is a fragmentary elevational view of the preferred embodiment of the apparatus present invention showing placement of the head and washer portions upon the shaft;

FIG. 5 is a fragmentary elevational view of the preferred embodiment of the apparatus of the present invention showing a rotational movement of washer, head and shaft;

FIG. 6 is a fragmentary perspective view of the preferred embodiment of the apparatus of present invention illustrating the shaft portion thereof;

FIG. 7 is a fragmentary perspective view of the preferred embodiment of the apparatus present invention showing the shaft, head and washer portions thereof;

FIG. 8 is a fragmentary perspective view of the preferred embodiment of the apparatus of present invention showing be head portion thereof;

FIG. 9 is a fragmentary perspective view of the preferred embodiment of the apparatus of the present invention showing the washer and shaft portions thereof;

FIG. 10 is a top view of the head portion of the preferred embodiment of the apparatus of present invention;

FIG. 11 is a sectional elevational view of the head portion of the preferred embodiment of the apparatus of present invention;

FIG. 12 is an elevational view of the preferred embodiment of the apparatus of the present invention illustrating the head portion thereof;

FIG. 13 is a bottom view of the head portion of the preferred embodiment of the apparatus of present invention;

FIG. 14 is a top view of the washer portion of the preferred embodiment of the apparatus of the present invention;

FIG. 15 is a sectional view of the washer portion of the preferred embodiment of the apparatus of the present invention;

FIG. 16 is a fragmentary sectional view of the washer portion of the preferred embodiment of the apparatus of the present invention;

FIG. 17 is a fragmentary sectional view of the washer portion of the preferred embodiment of the apparatus and present invention;

FIG. 18 is a perspective view of the preferred embodiment of the apparatus of the present invention showing implantation of an intramedullary rod and a plurality of the bone screws of the present invention securing the intramedullary rod to the patient's bone tissue;

FIG. 19 is a fragmentary perspective view of an alternate embodiment apparatus of the present invention showing the washer portion thereof; and

FIG. 20 is a fragmentary perspective view of the alternative embodiment of the apparatus present invention showing the washer and shaft portions thereof;

FIG. 21 is a perspective view of the alternate embodiment of the apparatus present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

FIGS. 1–5 show generally be preferred embodiment of the apparatus of the present invention designated generally

by the numeral 10 in FIG. 1. Bone screw apparatus 10 includes an elongated shank 13 that can be surgically implanted into a patient's bone tissue 11. In FIGS. 1 and 2, bone tissue 11 is shown having an outer surface 12 that is engaged by the lower or distal 15 end portion of shank 13. Shaft 13 has a proximal 14 end portion with a plurality of flat surfaces 17 that define a tool receptive surface for attachment to a drill chuck 21 or like driver tool.

Elongated shank 13 (see FIGS. 1–2 and 6–9) has a continuous helical thread 18 that extends substantially the full-length of shank 13. Shank 13 also provides a pair of longitudinally extending opposed flat surfaces 19,20. As shown in FIGS. 6–7, the surfaces 19,20 are about one hundred eighty (180°) degrees apart. The elongated shank 13 is preliminarily embedded into a patient's bone tissue 11 using drill chuck 21 (see FIG. 1). In FIGS. 1 and 5, shank 13 rotates in the direction of curved arrow 23. Once the shank 13 has been embedded into the bone tissue 11 a selected depth, the surgeon and uses his or her hand 23 to slide head 25 and washer 26 into position as shown at surface 12 of bone tissue 11. This sliding movement of the combination of head 25 and washer 26 is designated generally by the arrow 24 in FIGS. 2–3. The surgeon then cuts shank 13 as shown in FIG. 3 next to washer 25 to complete the implantation, this removing the excess, exposed shank material that is designated as 13A in FIG. 3.

In FIGS. 6–18, the construction and of head 25 and washer 26 are shown more particularly. Head 25 has a central opening 27 that fits over and conforms to the outer surface of shank 13. The opening 27 is defined by a pair of opposed flat surfaces 28 and a pair of opposed curved surfaces 29. A central raised portion 38 of head 25 has a pair of opposed slots 30 that communicate with opening 27. The central raised portion 38 includes two (2) raised sections 38A and 38B. Head 25 has an annular groove 31 surrounded by an annular shoulder 32. The underside 33 of head 25 has a plurality of cutting elements 34.

Each cutting element 34 is defined by a recess 35 that includes curved surface 36 and flat surface 40. The raised portion 38 and the raised sections 38A and 38B provide a plurality of flat surfaces 40–47 that enable a user to attach a hex driver, socket tool, or the like to the raised portion 38. The flat surfaces 40–47 can define a hexagonally-shaped surface to which a driver tool can attach. This attachment of a driver tool to raised portion 38 enables the entire screw apparatus 10 to be removed by rotating apparatus 10 with the driver tool in a counterclockwise direction, opposite the direction of curved arrow 23.

Ratcheting washer 26 has an annular periphery 48 and a central circular opening 49. A pair of ratcheting members 50,51 are provided on washer 27, spaced apart by one hundred eighty (180°) degrees. Circular opening 49 is defined by a pair of opposed curved surfaces 52,53 shown in FIG. 14. In FIGS. 15–17, ratcheting members 50,51 are shown, each including an inclined surface 54,55 respectively. Opposite each inclined surface 54,55 there is provided thread portions 56,57 alternating with grooves 58,59 (see FIG. 15). The threads 54, 55 and grooves 58, 59 engage helical thread 18 on shank 13.

In FIG. 18, a patient's femur is the bone tissue 11 into which a plurality of bone screws 10 have been implanted. The bone screws 10 are shown in FIG. 18 securing intramedullary rod 60 within the intramedullary canal of a patient's femur 11.

In FIGS. 19–21, and alternate construction of the washer portion of the present invention is shown, designated gen-

erally by the numeral 61. Washer 61 and FIGS. 19–20 as a circular periphery 62 and a hexagonally-shaped opening 63. Ratcheting members 64,65 are integrally formed with ring 61. Inwardly projecting tabs 66,67 engaged the threads 18 of shank 13 during use as shown FIGS. 20 and 21. As with washer 26, the washer 61 occupies annular groove 31 of head 25 at shown in FIG. 21.

The present invention enables a surgeon to embed shank 13 a desired distance into patients' bone tissue 11. The surgeon can be attached head 25 and ratcheting washer 26 to shank 13. During use, the surgeon first places the washer 26 into annular groove 31 of head 25. The surgeon then aligns the ratcheting members 50,51 with longitudinally extending surfaces 19,20. When the ratcheting members 50,51 are aligned with the longitudinally extending surfaces 19,20 the surgeon can easily slide the combination of the head 25 and washer 26 substantially the full-length of shank 13 at showing FIG. 2.

In FIGS. 3–5, the surgeon severs excess portion 13A of shank 13 above the head 25 as shown in FIG. 3. In FIG. 5, the head 25 is sufficiently exposed so that the surgeon can attach a driver tool to rotate the head 25 and attached shank 13 in the direction of arrow 23. This causes the underside 33 of head 25 to engage the surface 12 of bone tissue 11. As the head 25 is rotating, the plurality of cutting-edges 34 countersink head 25 into bone tissue 11 at surface 12.

The following table lists the parts numbers and parts descriptions as used herein and in the drawings attached hereto.

PARTS LIST	
Part Number	Description
10	bone screw apparatus
11	bone tissue
12	bone surface
13	elongated shank
13A	excess shank material
14	proximal end
15	distal end
16	cutting tip
17	flat surfaces
18	continuous helical thread
19	longitudinal flat slide surface
20	longitudinal flat slide surface
21	drill chuck
22	surgeon's hand
23	curved arrow
24	arrow
25	head
26	ratcheting washer
27	opening
28	flat surface
29	curved surface
30	slot
31	annular groove
32	annular shoulder
33	underside
34	cutting element
35	recess
36	curved surface
37	flat surface
38	central raised portion
38A	raised section
38B	raised section
39	central raised portion
40	flat surface
41	flat surface
42	flat surface
43	flat surface
44	flat surface
45	flat surface

-continued

PARTS LIST	
Part Number	Description
46	flat surface
47	flat surface
48	annular periphery
49	circular opening
50	ratchet member
51	ratchet member
52	curved surface
53	curved surface
54	inclined surface
55	inclined surface
56	thread
57	thread
58	groove
59	groove
60	intramedullary rod

The foregoing embodiments are presented by way of example only; the scope of the present invention is to be limited only by the following claims.

We claim:

1. A bone screw apparatus comprising;

- an elongated shaft having proximal and distal end portions, the distal end portion having a cutting head and the proximal end portion being sized and shaped to fit a driver tool such as a drill chuck;
- the shaft being externally threaded along at least a portion of its length and having at least one longitudinally extending shaped surface thereon;
- a removable head with a central opening that enables the head to slide along the shaft;
- means for preventing sliding movement of the head along the shaft distal to proximal;
- the head central opening being shaped to conform to the shaped surface of the shaft so that the head and shaft can be rotated as a unit by engaging and rotating the head; and
- a tool receptive surface portion of the head that accepts a driver tool for rotating the head and the connected shaft.

2. The bone screw apparatus of claim 1 wherein the shaft is threaded along a majority of its length.

3. The bone screw apparatus of claim 1, wherein there are two longitudinally extending surfaces positioned 180 degrees apart on the shaft.

4. The bone screw apparatus of claim 1, wherein the tool receptive surface portion of the head provides a hexagonally-shaped surface.

5. The bone screw apparatus of claim 1, wherein the means for preventing movement of the head in one direction is defined by a pair of opposed tabs with ratcheting portions.

6. The bone screw apparatus of claim 5, wherein the tabs are positioned about 180 degrees apart on opposing sides of the head.

7. The bone screw apparatus of claim 1, wherein the head has a convex annular distal surface.

8. The bone screw apparatus of claim 1, wherein the head has an internal thread for engaging the external thread of the shaft.

9. The bone screw apparatus of claim 1, wherein the head is comprised of a pair of independently movable, separable members.

10. A bone screw apparatus comprising;

- an elongated shaft having proximal and distal end portions, the distal end portion having a cutting head

and the proximal end portion being sized and shaped to fit a driver tool such as a drill chuck;

- b) the shaft being externally threaded along a majority of its length and having a plurality of longitudinally extending, circumferentially spaced apart shaped surfaces thereon;
- c) a removable head with a central opening that enables the head to slide along the shaft;
- d) the head having ratchets thereon that prevent sliding movement of the head along the shaft in a distal to a proximal direction;
- e) the head central opening being shaped to conform to the shaped surfaces of the shaft so that the head and shaft can be rotated as a unit by engaging and rotating the head; and
- f) a tool receptive surface portion of the head that accepts a driver tool for rotating the head and the connected shaft.

11. The apparatus of claim 10 wherein the tool receptive surface portion of the head includes intersecting external surfaces.

12. A method of implanting a bone screw through a patient's bone tissue, comprising the steps of:

- a) inserting a bone screw shaft into a patient's bone tissue, the shaft having an external surface with shaped longitudinally extending portions;
- b) placing a removable head on the shaft after the shaft is embedded in step "a" by sliding the head proximally to distally along the shaft until the head engages the patient;
- c) severing the shaft proximally of the head; and
- d) interlocking the head and shaft so that they rotate together.

13. The method of claim 12 wherein the interlocking automatically occurs in step "b".

14. The method of claim 12 wherein in steps "b" and "d" the head is a two part structure that includes first and second interlocking head segments and further comprising the step of connecting the first and second head segments together.

15. The method of claim 12, further comprising the step of engaging the threads of the shaft with an internally threaded portion of the head.

16. The method of claim 12 wherein in step "a" the shaft is threaded along a majority of its length.

17. The method of claim 12 further comprising the steps of "c" and "d", of sliding the head to a position next to the patient's bone tissue and further comprising the step of rotating the head relating to the shaft until the head engages the patient's bone tissue.

18. The method of claim 12 further comprising the step of removing the assembly of shaft and head by rotating the head with a driver tool.

19. A method of implanting a bone screw through a patient's bone tissue, comprising the steps of:

- a) inserting a bone screw shaft into a patient's bone tissue, the shaft having an external surface with shaped longitudinally extending portions;
- b) placing a removable head on the shaft after the shaft is embedded in step "a" by sliding the head in a proximal to distal direction along the shaft until the head engages the patient;
- c) severing the shaft proximally of the head;
- d) interlocking the head and shaft so that they rotate together; and
- e) further comprising the step between step "b" and "c" of disallowing movement of the head in a distal to proximal direction with a ratchet mechanism.

20. The method of claim 19 wherein the interlocking automatically occurs in step "b".

21. The method of claim 19 wherein in steps "b" and "d" the head is a two part structure that includes first and second interlocking head segments and further comprising the step of connecting the first and second head segments together.

22. The method of claim 19, further comprising the step of engaging the threads of the shaft with an internally threaded portion of the head.

23. The method of claim 19 wherein in step "a" the shaft is threaded along a majority of its length.

24. The method of claim 19 further comprising the steps of "c" and "d", of sliding the head to a position next to the patient's bone tissue and further comprising the step of rotating the head relating to the shaft until the head engages the patient's bone tissue.

25. The method of claim 19 further comprising the step of removing the assembly of shaft and head by rotating the head with a driver tool.

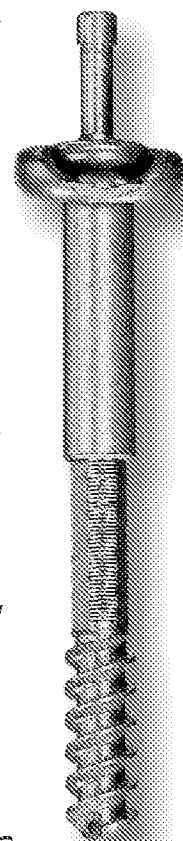
\* \* \* \* \*

10/623,193  
July 18, 2003

**EXHIBIT 4**

# BONE-LOK<sup>®</sup>

**OFTEN IMITATED,  
NEVER DUPLICATED<sup>™</sup>:**  
THE TRANSFACET-PEDICULAR  
COMPRESSION IMPLANT  
FOR LUMBAR STABILIZATION,  
WITH PATENTED CLASP<sup>®</sup>  
TECHNOLOGY, FROM  
INTERVENTIONAL SPINE<sup>®</sup>, INC.



- **ONLY** the patented BONE-LOK Implant has CLASP (Compression Locking Anchor with Secondary Purchase) technology.
- CLASP technology has three unique benefits over a lag screw:
  - 1) Superior pullout strength
  - 2) Superior compression strength
  - 3) Intraoperative flexibility

**ACCEPT NO SUBSTITUTE  
FOR YOUR PATIENTS.**

# BONE-LOK® Implants with CLASP® Technology

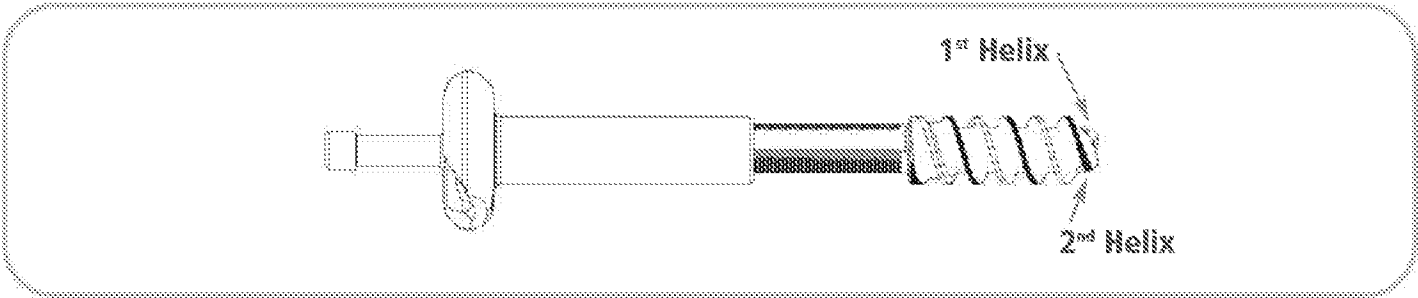
## Introduction

BONE-LOK Implants with CLASP (Compression Locking Anchor with Secondary Purchase) technology were developed to address fixation problems associated with current lag screw technology. Adequate compression is an important factor for fixation. The BONE-LOK Implant has a unique ratcheting collar that separates anchor insertion and compression into two steps (secondary compression). This patented ratcheting collar mechanism is what Interventional Spine refers to as CLASP technology. CLASP Technology has three unique benefits over current lag screw technology:

- 1) Superior pullout strength
- 2) Superior compression strength
- 3) Intraoperative flexibility

## Superior Pullout Strength

The unique double helix thread design of the BONE-LOK device provides superior pullout strength to standard screw threads (single helix). The double helix is two screw threads on one shaft offset 180 degrees from each other as shown below:



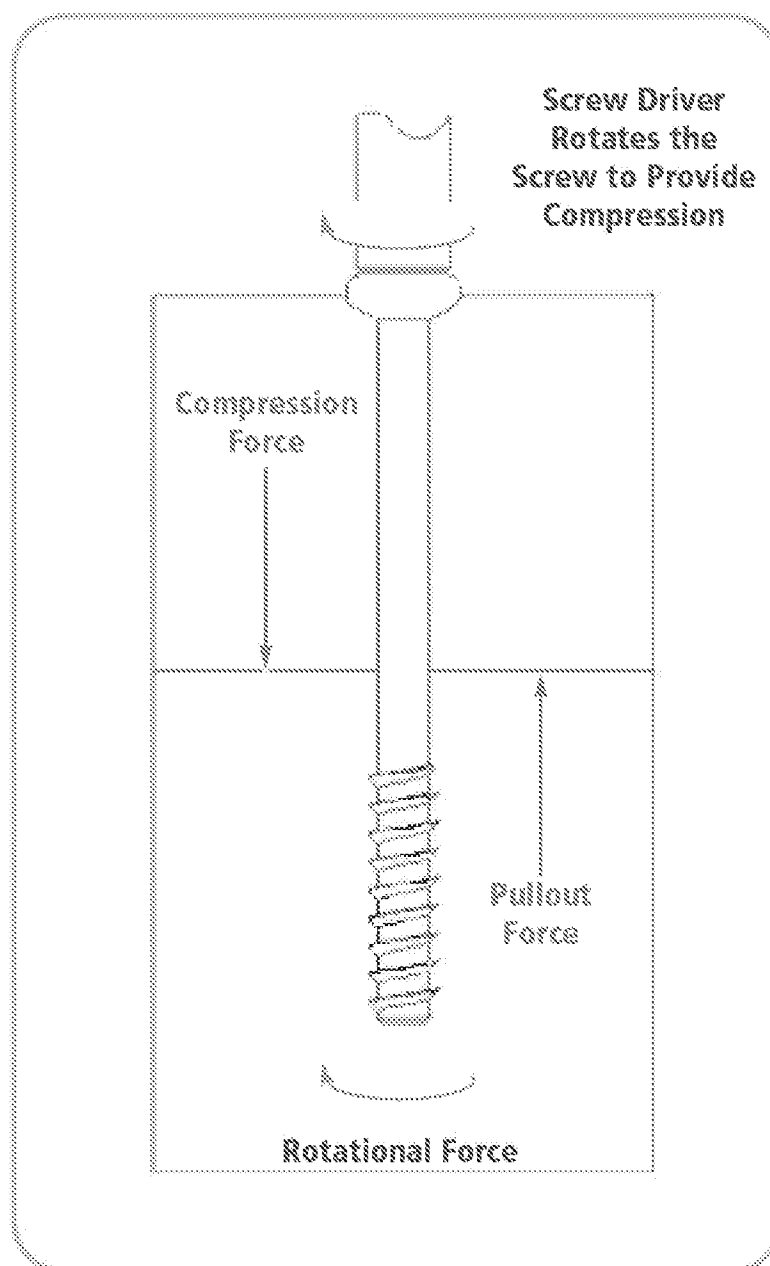
Typically, low threads per inch (TPI) threads are used for cancellous or “bad” bone. Higher TPI threads are used for cortical or dense bone. The double helix is comprised of two low TPI threads intertwined to become an overall higher TPI thread device. The design preserves features of both TPis for use in all bone qualities. Increased pullout strength results in higher compression strength (see below) and can prevent postoperative screw loosening that occurs with current lag screws.

	Foam Density	BONE-LOK® Implant 4.5mm	LAG SCREW NuVasive Triad® 4.5mm
Foam Pullout (avg.)	7lb/ft³	88.52 N	71.56 N
	12lb/ft³	184.12 N	150.38 N

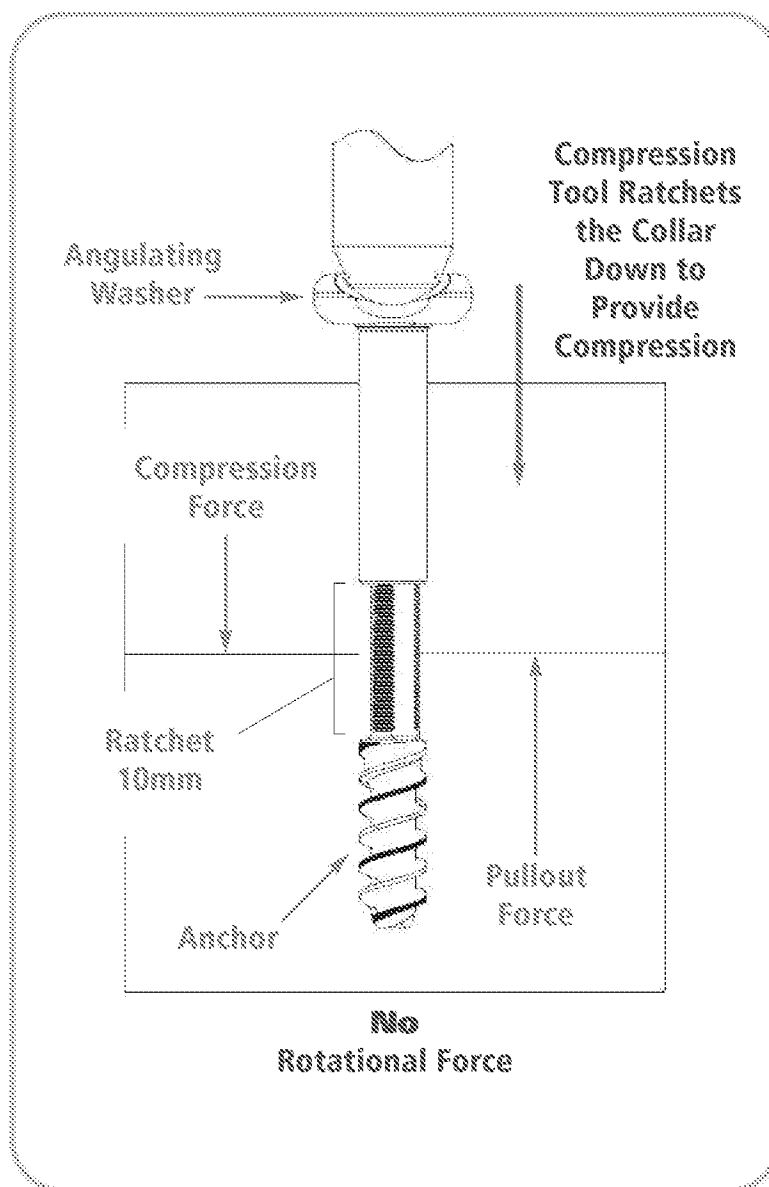


Interventional Spine has separated anchor placement and compression into two steps. The BONE-LOK device is comprised of four components: Angulating Washer, Dual Helix Anchor, Adjustable Collar and Pull Pin. With a lag screw, compression is achieved by rotating the lag screw into the bone and when the head of the screw comes into contact with the proximal cortex, compression is realized. As opposed to a lag screw, the BONE-LOK anchor is positioned into the bone first and compression is applied as a secondary step. *The elimination of the anchor movement during compression is the primary reason why the BONE-LOK Implant with CLASP technology achieves superior compression to a typical lag screw.*

### For a lag screw:



**For BONE-LOK® Implant:**



Compression Strength (avg.)	Foam Density	BONE-LOK® Implant 4.5mm	LAG SCREW NuVasive Triad® 4.5mm
	7lb/ft³	121.7 N	84.78 N
	12lb/ft³	197.9 N	136.47 N

Complete test is on file at Interventional Spine, Inc.

## Intraoperative Flexibility

Another key benefit of CLASP Technology is that it provides surgeons intraoperative flexibility. Each BONE-LOK device comes with a built in 10mm length range, as opposed to a fixed length found in a lag screw. *In effect the BONE-LOK Implant has a one size-fits-all characteristic unique to the design. Sizing is achieved in vivo.*

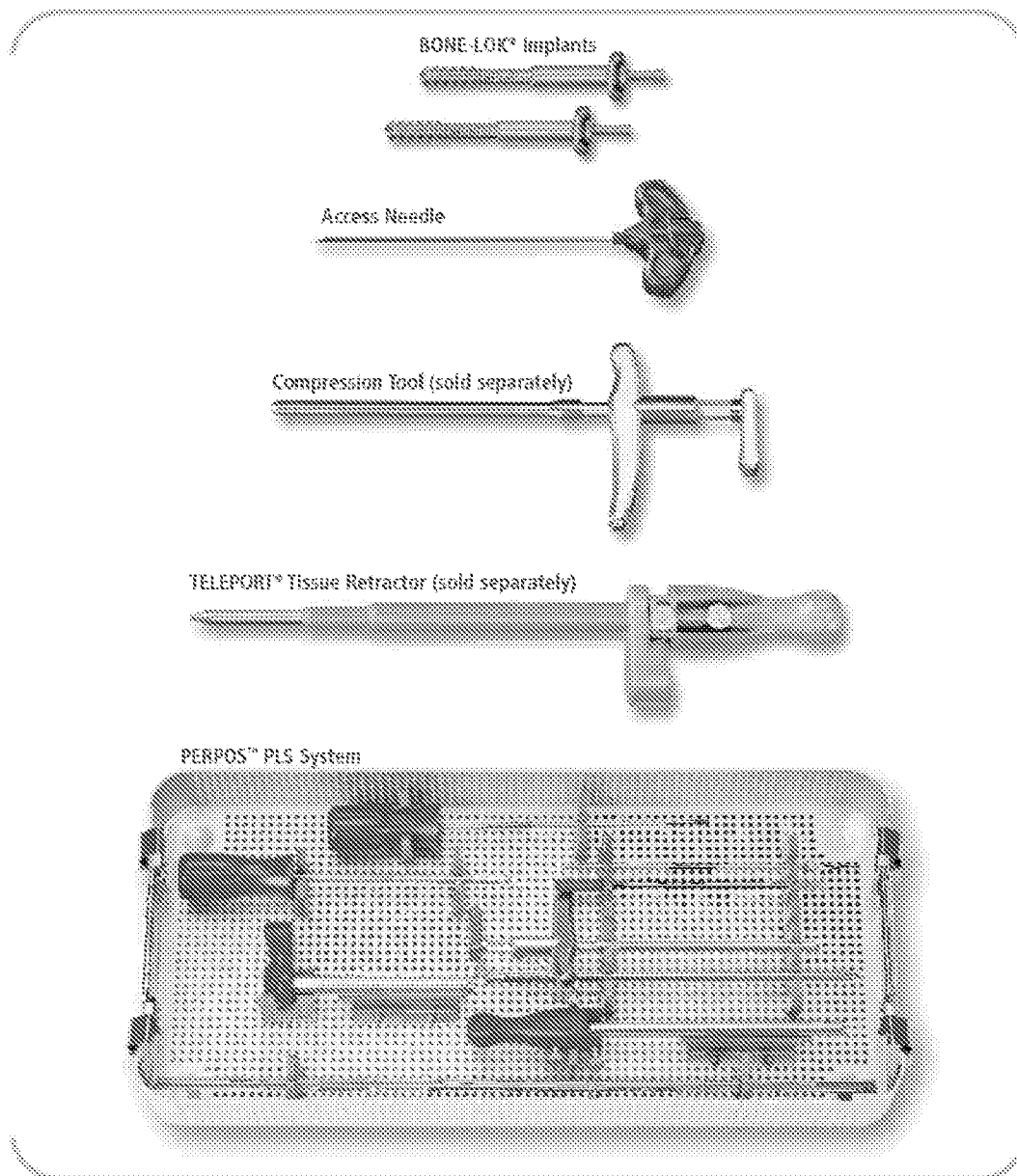
Not only does this significantly reduce inventory, but provides surgeons the intraoperative flexibility to precisely position the tip of the BONE-LOK device to maximize its purchase. For a variety of reasons, surgeons have reported selecting the wrong length screw. A screw that is too long may not provide as much compression as desired because it can only be screwed in so far (stops at the distal cortex) or can penetrate through the distal cortex into adjoining tissue that may include nerve roots or spinal cord. These situations can cause the patient pain and/or tissue irritation and/or healing problems as well more serious conditions. A screw too short can result in lower compression or complete loss of purchase, which results in fixation problems as described before. Using the BONE-LOK Implant makes choosing the correct screw size one less thing for the surgeon to be concerned with. Typical lag screws only come in 5mm size increments. With the BONE-LOK Implant, a surgeon can accurately compress to an exact size in vivo while maximizing compression and purchase.

## Summary

BONE-LOK Implants with CLASP Technology provides higher compression strength which can lead to better stability and likelihood of fusion. It can also prevent postoperative loosening as well as providing intraoperative flexibility for surgeons.

# PERPOS™ PLS System

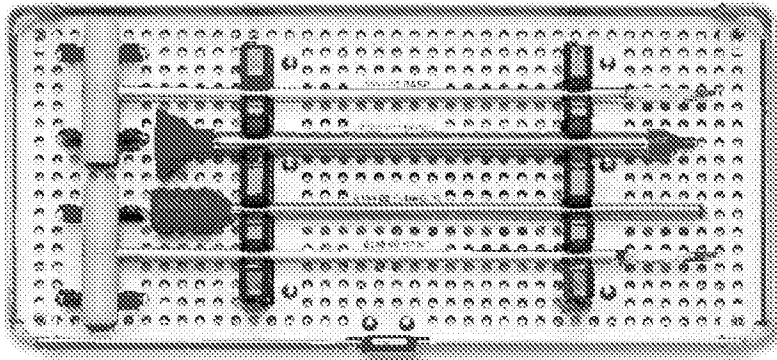
The *first* and *only*  
PERCUTANEOUS transfacet-pedicular  
compression system for posterior  
stabilization during a fusion procedure  
of the lower spine.



- ONLY the BONE-LOK implant can be implanted with the PERPOS PLS System and the Teleport® Tissue Retractor to achieve PERCUTANEOUS lumbar stabilization.

# PERPOS-Fuse™

**100% PERCUTANEOUS Facet-Pedicular System for Fusion**  
using the PERPOS™ PLS System, the  
**BONE-LOK®** Implant, and the  
**PERPOS Fusion Facet Prep Kit**,  
from Interventional Spine



In addition, a PERPOS™ Fusion Facet Prep Kit can be used in conjunction with the PERPOS PLS System to promote fusion of the facet joints. Fusion of the facet joints provides an added element of spinal stability to the treated segment.



Early post-operative AP radiograph showing bilateral BONE-LOK® device at L5-S1.

- The PERPOS PLS System including the BONE-LOK Implant and the PERPOS Fusion Facet Prep Kit can provide secure bilateral immobilization of the facet joints, allowing the normal healing process to create fusion.
- A PERPOS-Fuse procedure combines demonstrated stability through transfacet-pedicular compression with; ease of use, time savings, over the wire control, and mated cannulated instrumentation.
- A PERPOS-Fuse procedure can reduce patient trauma and recovery time when compared to open surgical procedures for fusion.
- A PERPOS-Fuse procedure is cost effective: as the one size fits all BONE-LOK Implant reduces inventory; the PERPOS PLS System reduces demands on central sterilization units; and OR room and staff support time can be reduced with bilateral BONE-LOK Implants.



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Interventional Spine, Inc is certified to IS EN ISO 13485:2003.

Interventional Spine®, PERPOS™, BONE-LOK®, CLASP®, Teleport® are all marks registered with the U.S. Patent and Trademark Office.

Triad® is a registered trademark of NuVasive®, Inc

As of the date of print, Interventional Spine® has several issued and pending U.S. patents.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



The products have been assessed in conjunction with the Notified Body as applicable, and are considered to meet the Essential Requirements and so bear the CE Marking of Conformity.